MINISTRY OF HEALTH
OF THE CZECH REPUBLIC

TENDER DOCUMENTATION

FOR PUBLIC TENDER NO.1

IN RESEARCH, EXPERIMENTAL DEVELOPMENT AND INNOVATION

IN THE APPLIED HEALTH RESEARCH SUPPORT PROGRAM

FOR THE YEARS 2024 – 2030

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1. Basic Information

2. Public Tender

2.1. Tendering and Evaluation Period, Project Duration

(1) The public tender shall begin on the date of its publication in the Commercial Newsletter, via the Research, Development and Innovation Information System (VES) and shall be published on the website of the Provider on 16 May 2023 and shall end on the date of the announcement of the results of the public tender.

(2) The tendering period is the period during which Project proposals may be submitted. It starts on the day after the date of the call for proposals, i.e. on 17 May 2023, and ends at 12:00 noon on 29 June 2023.

(3) The evaluation period is the period during which the Provider conducts the evaluation of the Project proposals, makes a Decision and announces the results of the public tender. It starts from the day following the end of the call for proposals and ends on the day of the announcement of the results of the call for proposals. The evaluation period starts on 30 June 2023 and ends on 24 February 2024.

(4) The Project start date in this call for proposals is always 1 May 2024, the Project end date is 31 December 2027.

(5) The maximum duration of the Projects in this call for proposals is 44 months (1 May 2024-31 December 2027).

(6) The results of the tender will be published by 24 February 2024 at the latest on the website of the Provider – Public Tender 2024 – 2027 – Ministry of Health (www.mzcr.cz) and AZV www.azvcr.cz. Subsequently, the Provider shall inform the Applicants of the results of the public tender.

2.2. Funding for the Public Tender

(1) In this call for tenders, it is expected that approximately 200 million CZK will be distributed among the beneficiaries for the first year of the solving from the State budget, of which approximately 10% will be allocated to junior researcher Projects (Subprogram 2). For the following years, the allocation will depend on the volume and cost structure of the Projects accepted for Support, as well as on the possibilities of the State budget.

2.3. Rules for Determining the Intensity and Amount of Support

(1) For the purposes of establishing the intensity and amount of Support, the Applicant must assign the Project to a specific research category according to Article 25 of the Commission Regulation (basic research, industrial research, Development) in the Project proposal. In the event that the Project cannot be clearly assigned to a single research category, the Applicant must specify, in accordance with the Regulation, the shares of each category of research in the Project according to the activities carried out.

(2) The Support will be provided in the form of a subsidy for recognized costs to legal or natural persons, in the form of an increase in the expenditure of organizational units of the State or organizational units of ministries.

(3) The Support intensity, set as a percentage of the eligible Project costs, will be calculated for each Project and for each Beneficiary and other Participants separately on the basis of the results of the evaluation of the Project proposals, the financial limits of the possible expenditure of the program in the public call for proposals and in accordance with the Commission Regulation and the Framework. At the same time, it must respect all these limits.

(4) The amount of Support will be assessed individually for each Project. The amount of Support requested must be justified and proportionate to the objectives, duration and expected results of the Project.

(5) The maximum allowable Support intensity **for Research Organizations** per Project may be up to 100 % of the total eligible costs, for non-economic activities of Research Organizations in accordance with point 19 et seq. of the Framework and in accordance with the Act and the Commission Regulation and under the conditions set out in paragraph (8) of this Article.

(6) The permitted Support intensities **for each category of Enterprise** and for each category of research (basic research, industrial research and Development) are given in in Table 1.

Table 1:

<table>
<tr><th></th><th>Small Enterprise</th><th>Medium Enterprise</th><th>Large Enterprise</th></tr>
<tr><td>Basic research</td><td>100 %</td><td>100 %</td><td>100 %</td></tr>
<tr><td>Industrial research</td><td>70 %</td><td>60 %</td><td>50 %</td></tr>
<tr><td>Industrial research in the case of:</td><td rowspan="5">80 %</td><td rowspan="5">75 %</td><td rowspan="5">65 %</td></tr>
<tr><td>• effective cooperation between Enterprises;
for large Enterprises: cross-border cooperation with at least one small or medium-sized Enterprise</td></tr>
<tr><td>Or</td></tr>
<tr><td>• cooperation between an Enterprise and a Research Organization</td></tr>
<tr><td>Or</td></tr>
<tr><td>• public dissemination of results</td><td></td><td></td><td></td></tr>
<tr><td>Experimental development</td><td>45 %</td><td>35 %</td><td>25 %</td></tr>
<tr><td>Experimental development in the case of:</td><td rowspan="5">60 %</td><td rowspan="5">50 %</td><td rowspan="5">40 %</td></tr>
<tr><td>• effective cooperation between Enterprises;
for large Enterprises, cross-border cooperation or cooperation with at least one small or medium-sized Enterprise</td></tr>
<tr><td>Or</td></tr>
<tr><td>• cooperation between an Enterprise and a Research Organization</td></tr>
<tr><td>Or</td></tr>
<tr><td>• public dissemination of results</td><td></td><td></td><td></td></tr>
</table>

(8) The Applicant and the Co-applicant must comply with conditions that prevent that the funding of the Research Organization is direct or indirect State Support in terms of EU rules (in accordance with the Commission Regulation and the Framework) or that there is no double funding.

(12) Maximum allowable amount of Project Support (without notification obligation) and a more detailed assessment by the EC), which is established under Article 4(1) of the Commission Regulation, will not be exceeded.

(13) The Provider shall decide on the intensity and amount of Support from the State budget for the selected Project on the basis of the evaluation of the Project proposal. The Special-purpose Support may be changed during the course of the solution of the accepted Projects on the basis of the results of the control pursuant to Section 13 of the Act or in connection with a change in the amount of the recognized costs at the request of the Applicant, but not more than 50% pursuant to Section 9(7) of the Act.

3. Program Information

3.1. Objective of the Program

(1) The main objective of the Program is to contribute to the provision and further development of internationally competitive medical research in the Czech Republic, the level of which will be comparable to that of the developed countries of the European Union. The Program will enable the creation of new knowledge, the specific aim or objective of which will enable or aim at improving public health, clarifying the pathogenesis and development of diseases, or seeking innovative solutions for medicine, with a view to maintaining maximum efficiency in the use of public funds.

3.2. Subprograms

(1) The program is divided into two sub-programs, the criteria for division being the stage of the Investigators' career path. In terms of their professional focus, both sub-programs will fulfil the objectives of this Program as set out below.

(2) Sub-program 1:

The main objective of Subprogram 1 is to further develop the existing platform of applied medical research in the Czech Republic and to contribute to the further development of international cooperation by improving its conditions. Within the framework of Subprogram 1, only those Projects will be Supported in which the Principal Investigator is a natural person engaged in research who, at the time of submission of the Project proposal to the public tender, holds an academic degree of Ph.D., its equivalent or higher.

(3) Sub-program 2:

The main objective of Sub-program 2 is to Support the development of junior researchers in their research activities and to ensure the sustainability of the research environment in healthcare. Under Sub-program 2, Support will be given to Projects in which the Principal

Investigator is a natural person engaged in research who, in the year of submission of the Project proposal to the call for proposals, has received their Ph.D. academic title or its equivalent in the past 8 years, or has obtained it no later than the date of conclusion of the Contract/issuance of the Project Decision. If the Proposer has been on maternity or parental leave, has suffered a long-term illness, or has interrupted his/her scientific career for similar objective reasons, the time limit of 8 years from the award of the academic degree of Ph.D. or its equivalent is increased by this period. These facts (award of the degree, parental leave, etc.) shall be documented by the Applicant by means of an affidavit.

The amount of eligible Project costs under Sub-program 2 is limited to 7 million. CZK.

3.3. Program Areas

(1) The program is divided into three main areas: Public Health, Pathogenesis and Development of Diseases, and Innovative Solutions for Medicine, which are further subdivided into 26 sub-areas and 95 sub-objectives. The sub-objectives characterize each sub-area. Projects proposed for this Program must be assigned to one or more of the following sub-objectives and ensure the fulfilment of one or more sub-areas or Program areas. The Provider reserves the right to support Projects that do not fall within these sub-objectives or sub-areas.

Area 1. Public Health

Sub-area 1.1: Socioeconomic Aspects of Healthcare

Sub-objective 1.1.1: Collection, quality and application of data on healthcare and population behavior

Sub-objective 1.1.2: Program impact measurement and analysis of new programs or legislative proposals by government and independent experts

Sub-objective 1.1.3: Developing new methodologies and interdisciplinary collaboration in healthcare

Sub-objective 1.1.4: Social determinants of health and the gender dimension

Sub-area 1.2: Digitization of the Healthcare System

Sub-objective 1.2.1: Digitization will improve population health and the quality of health services

Sub-objective 1.2.2: Digitization will lead to improved accessibility and efficiency of health services and higher levels of data integration within the healthcare provider system

Sub-objective 1.2.3: Increased use of data sources in the Czech health system

Sub-area 1.3: Demographic Changes and Care for the Elderly

Sub-objective 1.3.1: Analysis of the structure of providers and social healthcare provided to the elderly population

Sub-objective 1.3.2: Analyzing and addressing the social and healthcare needs of the elderly (especially the very elderly)

Sub-objective 1.3.3: Early prevention of the occurrence and mitigation of the effects of involutional changes, including the use of modern technologies

Sub-objective 1.3.4: Promoting quality and safe patient care with regard to age-specific risks and the prevention of adverse events in the provision of long-term medical and nursing care

Sub-area 1.4: Healthcare

Sub-objective 1.4.1: Analysis of the need and consumption (utilization) of healthcare for persons with chronic diseases

Sub-objective 1.4.2: Measurability of healthcare outcomes

Sub-objective 1.4.3: Capacity, consumption and access to healthcare

Sub-objective 1.4.4: Human resources in healthcare

Sub-objective 1.4.5: Patients' participation rights and respect for the autonomy of their will

Sub-objective 1.4.6: Means of protecting the rights of persons in medical malpractice

Sub-area 1.5: Promoting Health Literacy and Patient Orientation

Sub-objective 1.5.1: Monitoring the level of health literacy in the Czech Republic

Sub-objective 1.5.2: Research on the competences and needs of health literacy actors

Sub-objective 1.5.3: Research of specific target groups of the National Health Literacy Program

Sub-objective 1.5.4: Research on specific areas of health literacy

Sub-objective 1.5.5: Health literacy competencies of health professionals

Sub-objective 1.5.6: Fighting unscientific views in healthcare

Sub-objective 1.5.7: Strengthening health literacy unencumbered by gender stereotypes

Sub-area 1.6: Health Promotion and Prevention

Sub-objective 1.6.1 Metabolic and endocrine diseases

Sub-objective 1.6.2. Diseases of the circulatory system

Sub-objective 1.6.3. Cancers

Sub-objective 1.6.4. Chronic lung diseases

Sub-objective 1.6.5 Blood diseases

Sub-objective 1.6.6. Nervous and mental diseases

Sub-objective 1.6.7 Diseases of the musculoskeletal system and inflammatory and immunological diseases

Sub-objective 1.6.8. Addictions

Sub-area 1.7: Global Health

Sub-objective 1.7.1: Environmental and occupational health effects

Sub-objective 1.7.2: The influence of nutrition and eating habits on health

Sub-objective 1.7.3: Infectious diseases

Sub-objective 1.7.4: Toxicology and health safety

Sub-objective 1.7.5: Occupational medicine and diseases

Sub-objective 1.7.6: Innovative approaches to health promotion and intervention programs in primary prevention

<u>Area 2. Pathogenesis and Development of Diseases</u>

Sub-area 2.1: Metabolic and Endocrine Diseases

Sub-objective 2.1.1: Etiology and pathophysiology of the metabolic syndrome

Sub-objective 2.1.2: Etiology and pathogenesis of immune-mediated endocrine diseases

Sub-objective 2.1.3: Pathogenesis and treatment of complications of diabetes

Sub-area 2.2: Diseases of the Circulatory System

Sub-objective 2.2.1: Elucidation of etiological factors and pathophysiological processes affecting the development and course of cardiovascular and cerebrovascular diseases

Sub-objective 2.2.2: Development of early diagnostics of cardiovascular and cerebrovascular diseases and finding treatment modalities and procedures in the therapy of these diseases with higher therapeutic efficiency and greater gentleness for the patient

Sub-area 2.3: Cancers

Sub-objective 2.3.1: Advancing knowledge of the pathogenesis and development of cancer and identifying new therapeutic targets

Sub-objective 2.3.2: Improving the diagnosis and treatment of cancer, especially through the implementation of precision medicine, modern therapeutics, targeted drugs and modern radiotherapy

Sub-objective 2.3.3: Improving the quality of life of cancer patients through a better understanding of the factors that accompany cancer and its treatment

Sub-area 2.4: Chronic Lung Diseases

Sub-objective 2.4.1: Influencing previously untreatable and progressive chronic diseases in terms of stopping the progression or finding ways to reverse the process

Sub-objective 2.4.2: Establishing new therapies by repurposing or combining existing drugs with known targeted drugs, proposals for new treatment modalities based on phenotype-specific markers of pathogenesis

Sub-area 2.5: Blood Diseases

Sub-objective 2.5.1: Advancing knowledge in the pathogenesis and development of blood diseases and identifying new therapeutic targets

Sub-objective 2.5.2: Improvement in the diagnosis and treatment of blood diseases, especially through the implementation of precision medicine, modern therapeutics, targeted drugs and modern radiotherapy

Sub-objective 2.5.3: Improving the quality of life of patients with blood diseases by understanding the factors that accompany cancer and its treatment

Sub-area 2.6: Nervous and Mental Diseases

Sub-objective 2.6.1: Mental and neurological diseases

Sub-objective 2.6.2: Diagnosis of diseases of the nervous system

Sub-objective 2.6.3: Improved effectiveness of treatments for diseases of the nervous system

Sub-objective 2.6.4: Ensuring quality of life in patients with diseases of the nervous system

Sub-area 2.7: Musculoskeletal and Inflammatory Diseases

Sub-objective 2.7.1: Etiology and pathogenesis of degenerative and metabolic diseases of the musculoskeletal system

Sub-objective 2.7.2: Research in the field of musculoskeletal traumatology

Sub-area 2.8: Immunopathological Diseases

Sub-objective 2.8.1: Defining the determinants of immunopathological diseases and identifying new targets for diagnosis and targeted treatment of these diseases

Sub-area 2.9: Infectious Diseases

Sub-objective 2.9.1: Etiology and therapy of important infectious diseases

Sub-objective 2.9:2: Epidemiology of antimicrobial resistance

Sub-objective 2.9.3: New diagnostic methods

Sub-objective 2.9.4: A new anti-infective

Sub-area 2.10: Diseases of the Perinatal Period and Childhood

Sub-objective 2.10.1: Diseases arising prenatally, perinatally and in early childhood

Sub-objective 2.10.2: Rare diseases

Sub-objective 2.10.3: Chronic immunopathological diseases with an environmental component

Area 3: Innovative Solutions for Medicine

Sub-area 3.1: Personalized Medicine and New Diagnostic and Theranostic Procedures

Sub-objective 3.1.1: High-throughput molecular biology methods and bioinformatics tools for personalized medicine

Sub-objective 3.1.2: Genome sequencing (WGS) of a selected sample of the Czech population

Sub-objective 3.1.3: Research and development of innovative diagnostic and theranostic tools

Sub-objective 3.1.4: Personalized disease prevention

Sub-objective 3.1.5: Personalized therapy

Sub-area 3.2: Low-Molecular-Weight Pharmaceuticals

Sub-objective 3.2.1: New low-molecular-weight pharmaceuticals

Sub-objective 3.2.2: Identification of new therapeutic targets, new methods and procedures for biological testing

Sub-area 3.3: Advanced Therapy Medicinal Products

Sub-objective 3.3.1: Research and development of gene therapy medicinal products

Sub-objective 3.3.2: Research and development of medicinal products for somatic cell therapies

Sub-objective 3.3.3: Research and development of tissue-engineered products

Sub-objective 3.3.4: Precision genomics as a tool to optimize and stratify patients suitable for gene and somatic cell therapies

Sub-objective 3.3.5: Supporting proof-of-concept Phase I/II clinical trials to evaluate the safety and efficacy of advanced therapy medicinal products

Sub-objective 3.3.6: Ethical, legal, regulatory and socio-economic aspects of research, development and treatment of patients using ATMP medicines

Sub-area 3.4: Biologicals Medicines, Including Prophylactic and Therapeutic Vaccines

Sub-objective 3.4.1: New biologic drugs

Sub-objective 3.4.2: New vaccines for disease prevention and treatment

Sub-area 3.5: New Drug Formulations

Sub-objective 3.5.1: Development of novel drug-delivery systems for time- and site-specific drug release

Sub-objective 3.5.2: Systems for pharmacotherapy-resistant diseases and for overcoming biological barriers

Sub-objective 3.5.3: Introduction of new formulation technologies into research, development and production of pharmaceutical forms

Sub-area 3.6: Development and Research in the Field of New Medical Devices and Equipment

Sub-objective 3.6.1: Development and research of medical imaging techniques

Sub-objective 3.6.2: Development of minimally invasive treatment techniques and their comparison with classical procedures

Sub-objective 3.6.3: Development in the field of navigation and robotic systems

Sub-objective 3.6.4: Research and development in the field of medical implants – neurostimulators and cardiac implants

Sub-area 3.7: Innovative Research in Surgery, Including Transplantation

Sub-objective 3.7.1: Non-invasive treatment

Sub-objective 3.7.2: Hybrid performances

Sub-objective 3.7.3: Tissue and organ replacement

Sub-objective 3.7.4: Treatment procedures

Sub-area 3.8: Telemedicine and eHealth

Sub-objective 3.8.1: Creation of a data environment enabling the main objective

Sub-area 3.9: Innovative Practices in Palliative and Supportive Care

Sub-objective 3.9.1: Effective organization of health services for patients in palliative care

Sub-objective 3.9.2: Competence of health professionals in communication and ethics

Sub-objective 3.9.3: Innovative approaches to symptom management in palliative care

(2) The detailed specification of the individual areas, sub-areas and sub-objectives is set out in the Program, which is available on the Provider's website at https://www.mzcr.cz/program-na-podporu-zdravotnickeho-aplikovaneho-vyzkumu-na-leta-2024-2030-kod-nw/ and the National Strategy for Medical Research Until 2030 at https://www.mzcr.cz/koncepce-zdravotnickeho-vyzkumu-do-roku-2030/.

(3) It is not possible to submit Project proposals to the tender that consist in clinical trials of medicines according to the provisions of Act No. 378/2007 Coll., on Medicinal Products and on the amendment of some related acts, as amended (hereinafter referred to as the "**Medicinal Products Act**"), or clinical testing of medical devices pursuant to Act No. 375/2022 Coll, on medical devices and in vitro diagnostic medical devices, as amended (hereinafter referred to as the "**Medical Devices Act**"), which are not registered or which would require a change in the registration, including an amendment procedure (i.e. a change in the drug substance, form of administration, strength, package size, use of an approved medical device other than as declared by the manufacturer, etc.), **except for clinical trials conducted by non-commercial sponsors**. The Proposer of the clinical trial must be the Applicant/Co-applicant. The health service Provider does not have to be the Proposer of the clinical trial, but must always be the Applicant/Co-applicant (or future Beneficiary/Co-beneficiary).

(4) It is not possible to submit to the tender a Project proposal whose aim is to create a registry that corresponds in nature to the national health registry, the creation and administration of which is regulated by Act No 372/2011 Coll., on health services and conditions of their provision, as amended. Individual Projects may include the creation of a registry that is a database

(collection of specific data that will be used to address the Project objectives), but the final goal of the Project is to achieve new knowledge.

4. Applicants and Proof of Eligibility

4.1. Applicants

(1) The following persons may be Applicants for or Beneficiaries of Support from the Program for a Project under the Act, the Commission Regulation and the Framework, as well as Co-applicants (or other Participants) in the Project:

- Research Organizations – see Chapter 1.2. point (14)
- Enterprises – see Chapter 1.2. point (15)

(2) As a natural person, only an entrepreneur who carries out an economic activity and at the same time carries out an entrepreneurial activity in accordance with the Act may be an eligible Applicant. 455/1991 Coll., on trade business (Trade Licensing Act), as amended.

(3) The assessment of whether the Applicant or Co-applicant fulfils the defining characteristics of a Research Organization according to the Act, the Commission Regulation and the Framework will be carried out by the Provider for each Applicant or Co-applicant individually during the evaluation of the Project proposal, during the Project and after its completion.

4.2. Applicant Eligibility Requirements, Professional Competence (if the Nature of the Project Requires It) and the Method of Demonstrating Eligibility

(1) **Eligibility** for the proposed Project shall be demonstrated by the Applicant in accordance with the provisions of Section 18 (2) of the Act **at the time of submission of the Project proposal** as follows:

a) The professional prerequisites for the Project according to Section 18(2)(a) of the Act are demonstrated by the Applicant in the Project proposal in the section dealing with the justification of the proposal, while the Provider will assess these prerequisites with regard to the nature of the Project proposal, taking into account the content of the Project proposal and its financial scope according to the criteria set out in this Tender Documentation;

b) Authorization to operate under Section 18(2)(b) of the Act shall be submitted by those Applicants/Co-applicants who are not a public university[3] or public research institution[4] or for which the MoH is not the founder, by a copy of the proof of business authorization or other required authorization (e.g., certificate of incorporation or other

[3] Public universities established pursuant to Act No. 111/1998 Coll., on Higher Education and on Amendments and Supplements to Other Acts (Act on Higher Education), as amended

[4] Public research institutions established pursuant to Act No. 341/2005 Coll., on Public Research Institutions, as amended

similar document of establishment or incorporation, extract from the commercial register or other statutory list);

c) Eligibility under Section 18(2)(c) to (i) of the Act is demonstrated by the original or officially certified copy of the affidavit (according to TD Annex 2), while eligibility under Section 18(2)(e) and (f) of the Act is demonstrated in the case of legal entities by persons who act as the statutory body of the Applicant or its member (e.g. for public universities and public research institutions);
d) Each Applicant/Co-applicant that is a legal entity shall provide an affidavit of the Applicant/Co-applicant for the Project proposal as a Grant application under the Act 218/2000 Coll., on Budgetary Rules and on Amendments to Certain Related Acts, as amended (hereinafter referred to as the "**Act on Budgetary Rules**") – a sample of the affidavit is provided in TD Annex 3;
e) Each Applicant/Co-applicant that is a Research Organization shall provide an affidavit of its eligibility as a Research Organization – a model affidavit is provided in Annex 4 of the SO;
f) If the Project requires authorization under a specific legal regulation or other evidence (i.e. professional competence), all Applicants (or Co-applicants), regardless of legal form, shall submit such authorization or evidence by way of example:
    - scan of a document/license for certain handling of genetically modified organisms and products (according to Act No. 78/2004 Coll., on the handling of genetically modified organisms and genetic products, as amended) valid at least until the beginning of the Project;
    - scan authorization according to Act No. 285/2002 Coll., on donations, procurement and transplantation of tissues and organs and amending certain acts (Transplantation Act), as amended, valid at least until the beginning of the Project;
    - scan authorization according to Act No. 227/2006 Coll., on research on human embryonic stem cells and related activities and on amendments to some related acts, as amended, valid at least until the beginning of the Project;
    - scan of a valid authorization for the use of experimental animals – in the case of a proposed Project involving experimental work with animals, the Applicant shall attach to the Project proposal an **"Authorization for the Use of Experimental Animals"** (former accreditation of the user facility) pursuant to Section 15b of Act No. 246/1992 Coll, for the protection of animals against cruelty, as amended, valid at least until the start of the Project;
    - scan of a valid permit for the provision of health care services, if the Project will provide health care services by an entity that is not a health care institution (e.g. a University, the Czech Academy of Sciences);
    - scan of the patient's informed consent – if there is an experimental subject, enter the text of the informed consent of the patient/experimental subject who is familiar with the risks and benefits of participating in the Project and the option to withdraw from participation without consequences;

- scan of the opinion of the Applicant's/other Participant's ethics committee – see TD Annex 7;

g) The Applicant must provide a document regulating the relationship of the Project to the rules of the SÚKL:
   - in the case of a Project proposal that corresponds to a clinical trial of medicines, the Applicant shall attach an officially certified copy of the Decision on the authorization of a clinical trial for the Czech Republic within the meaning of the Medicines Act and the same documentation that was approved in this Decision;
   - in the case of a Project design corresponding to the conduct of a clinical trial for a medical device, the Applicant shall attach an officially certified copy of the SÚKL authorization to conduct a clinical trial for the medical device within the meaning of the Act on Medical Devices.

(2) An Applicant with whom a Contract is to be concluded for the provision of Special-purpose Support or in whose favor a Decision on a budget increase is to be made will be required to, **before the conclusion of the Contract or, in the case of an organizational unit of the State, before the Decision on the budget increase is made:**

a) It is required to provide a certified copy, not older than 90 calendar days, of the deed of incorporation, charter of incorporation or other document of establishment or incorporation upon the Provider's request, if this information about the Applicant cannot be found in any public administration information system.

b) For the purpose of proving the **authorization for activities** under Section 18 (2) (b) of the Act, if the Applicant intends to carry out such activities in the framework of the Project, the Applicant shall provide a certified copy of the authorization for activities not older than 90 calendar days. Only an entity established by the Ministry of Health or by a special law (e.g. Act No 111/1998 Coll., on universities and on amendments and supplements to other acts (Act on universities), as amended, Act No 341/2005 Coll., on public research institutions, as amended, etc.) shall not submit the authorization to operate.

c) The Provider shall also request the necessary cooperation from the Applicant by providing the data necessary for the submission of the request for an extract from the criminal record.

d) In accordance with the provisions of Section 14(3) of the Act on Budget Rules, the Applicant, which is a legal entity, shall submit the following in the form of an affidavit: 1. information on the identification of the persons acting on behalf of the Applicant, indicating whether they act as its statutory body or whether they act on the basis of a power of attorney, 2. information on the beneficial owner of the legal person in accordance with the law governing the registration of beneficial owners in the form of a full statement of the valid data and data which have been deleted without replacement or replaced by new data, if it is the person registering; where the Applicant for a subsidy is a foreign legal person, it shall provide evidence of its beneficial owner either by means of an extract from a foreign register similar to the register of beneficial owners

or, where no such foreign register exists, by providing the identification data of all persons who are the beneficial owner of the foreign legal person, and submit documents showing the relationship of all persons to the foreign legal person, in particular an extract from a foreign register similar to the commercial register, a list of shareholders, a decision of the statutory body on the payment of a share of profits, the memorandum of association, the articles of association or the articles of association, 3. information on the identification of the persons in whom it has a shareholding and the amount of such shareholding.

e) If the nature of the Project requires it, the Applicant shall attach a certified copy of a valid document/authorization for the specific handling of genetically modified organisms and products (see Act No. 78/2004 Coll., on the handling of genetically modified organisms and genetic products, as amended), authorization under Act No. 285/2002 Coll., on donation, procurement and transplantation of tissues and organs and on amendment of certain acts (Transplantation Act), as amended, authorization under Act No. 227/2006 Coll., on research on human embryonic stem cells and related activities and on amendment of certain related acts, as amended.

f) In the case of a proposed Project involving experimental work with animals, the applicant shall provide a **valid approved "Experiment Project"** relating specifically to this Project, or an officially certified copy thereof with the opinions of the expert committee of the user facility and the departmental committee of the relevant State authority pursuant to Act No. 246/1992 Coll. 419/2012 Coll., on the protection of experimental animals, as amended – see TD Annex 6.

g) If required by the nature of the Project, the Applicant shall attach a certified copy of the opinion of the Applicant's/other Participant's ethics committee relating to the Project – see TD Annex 6.

(3) Where one Applicant submits more than one Project proposal in a single call for tenders, it shall demonstrate its eligibility once, at the stage of submission of Project proposals in the manner specified in Article 4.2(1) and Article 8 of the TD, and at the stage of prior to the signing of the Grant Contract or the adoption of the Decision to increase the budget in accordance with Article 4.2(2) of the TD.

(4) An Applicant established outside the Czech Republic, who meets the conditions of Section 18 (11) of the Act, shall prove his/her eligibility pursuant to Section 18 (2) (b) to f) by means of an affidavit (a specimen of the affidavit is given in TD Annex 4). In accordance with the provisions of Article 1(5)(a) of the Regulation, it is required that the other Participant established outside the Czech Republic has an establishment or branch in the Czech Republic at the time of payment of the Support. At the same time, such an Applicant is obliged to prove, at the latest before the conclusion of the Support Contract, that the establishment or branch of a legal person established in a Member State of the European Union and located in the Czech Republic meets all the eligibility requirements under Section 18 of the Act, similarly to an Applicant established in the Czech Republic.

(5) Eligibility must be demonstrated in full, i.e. for all requirements and for all persons for whom such competence is demonstrated.

(6) Where an Applicant submits a Project proposal with a Co-applicant, the obligation to demonstrate eligibility shall apply to the Co-applicant and the provisions of Article 4.2(1) to (5) of the TD shall apply mutatis mutandis to the Co-applicant.

(7) According to the Commission Regulation, such an Enterprise cannot be a Beneficiary or a Participant, which has been issued with a recovery order (see Article 1(4)(a) of the Commission Regulation) and an Enterprise in difficulty (according to Article 1(4)(c) of the Commission Regulation)[5].

5. Project Proposal

5.1. Terms and Conditions of the Public Tender

(1) Project proposals may be submitted to the public tender only under the conditions defined by the Act and the TD.

(2) The Project proposal may not be changed during the tender. The Applicant, or a Co-Applicant through the Applicant, shall inform the Provider in writing any changes that have occurred between the submission of the Project proposal and the conclusion of the subsidy Contract, if any, or, in the case of a State organizational unit, the Decision to increase the budget for its solution, which affect its legal status or the data required for the demonstration of eligibility or data that could affect the evaluation of the Project proposal or data that could affect the conduct of the tender, within 7 calendar days of the date on which he/she became aware of such a fact by means of a data mailbox or to the email address of the Czech Health Research Council

[5] According to Article 2(18) of the Commission Regulation, an 'Enterprise in difficulty' is an Enterprise in which at least one of the following occurs one of the following circumstances:

(a) In the case of an LLC (which is not an SME and whose existence does not exceed three years or, for the purposes of eligibility for risk finance, which is not an SME within seven years of its first commercial sale and which is eligible for risk finance investment on the basis of due diligence carried out by a selected financial intermediary) where, as a result of an accumulation of losses, more than half of the subscribed share capital has been lost. This is the case when the result of deducting the accumulated losses from the reserves (and all other elements generally considered as Enterprise capital) is negative and exceeds half of the subscribed capital. For the purposes of this provision, a 'limited liability company' includes in particular the forms of companies listed in Annex I to Directive 2013/34/EU (1) and 'share capital' includes, where applicable, any share premium.

(b) In the case of an Enterprise in which at least some of the shareholders are fully liable for the obligations of the Enterprise (which is not an SME and which has been in existence for less than three years or, for the purposes of eligibility for venture capital financing, which is not an SME within seven years of its first commercial sale which, following due diligence by a selected financial intermediary, is eligible for venture capital financing investments), where the accumulation of losses has resulted in the loss of more than half of its capital as recorded in the accounts of that Enterprise. For the purposes of this provision a 'company in which at least some of the members are fully liable for the company's obligations' shall be deemed to be, in particular, the forms of Enterprise referred to in in Annex II to Directive 2013/34/EU.

(c) where collective insolvency proceedings have been opened against the Enterprise or the Enterprise meets the criteria under national law for opening collective insolvency proceedings at the request of its creditors.

(d) If the Enterprise has received rescue funding and has not yet repaid the loan or terminated the guarantee, or if it has received restructuring Support and is still subject to a restructuring plan.

(e) In the case of an enterprise which is not an SME, where in the last two years:

1) the Enterprise's book debt-to-equity ratio is greater than 7.5; and

2) the interest coverage ratio of the Enterprise's earnings before interest, taxes, depreciation and amortization (EBITDA) is less than 1.0.

info@azvcr.cz. In the event that the changes that have occurred could affect the course of the public tender, such a fact is a reason for the Project proposal to be excluded from the public tender.

(3) The Applicant may withdraw from the tender at any time by notifying the Provider (by letter signed by the Applicant's statutory representative and sent to the Provider's address).

(4) The Provider may cancel the tender under the conditions defined in Section 24 (1) to (4) of the Act

(5) Applicants shall not be entitled to reimbursement of costs associated with their participation in the tender.

5.2. General Conditions for Proposal Submissions

(1) The use of texts by other authors in the Project proposal must be supported by a bibliographic citation in the format according to ČSN ISO 690 and ČSN ISO 690-2, or according to citation practices in the field. The use of the adopted text without citation is a gross violation of the respected standards of scientific work and the terms of the TD.

(2) Only one Applicant may be named in a Project proposal.

(3) The same natural person may act as Proposer and Co-proposer for only one Project proposal in this call for proposals. If more Project proposals are received for the same natural person than the number specified in this condition, the Provider will retain in the call for tenders only the 2 Project proposals fulfilling the condition which were received earlier (the date and time of receipt of the Project proposal in the Provider's prescribed data box specified in the application for the management of this call for tenders is decisive).

(4) Project proposal forms are available exclusively on the websites of the Provider and the Czech Health Research Council of the Czech Republic at Public Tender 2024 – 2027 – Ministry of Health (www.mzcr.cz) and www.azvcr.cz in the ISVP web application created for this purpose (hereinafter referred to as the "**application**"). The Provider considers as a Project proposal only such a proposal which is created by the application and sent via a data message with the title (subject) "AZV – NW24-XX-00XXX"/ or "AZV – NW24J-XX-00XXX" (instead of "X" the relevant Project proposal numbers generated by the ISVP application will be added) to the AZV data box with the identifier "**f7eike4**". The Provider expressly points out that, for reasons of use of the application, Project proposals must be sent to the AZV mailbox. Project proposals sent to the Provider's mailbox will not be accepted for the tender. **Once finalized, the Project proposal will bear an electronic seal (signature), identifying the proposal. The proposal must not be modified in any way, otherwise this unique seal (signature) will be broken. Project proposals that have this seal altered will be excluded from the call for proposals.** Only the Annexes specified in Article 5.3 shall be attached to the Project proposal in the application. (14) of the TD and are required for the Project. Attachments must be uploaded to the application in PDF format. The attachment itself does not need to be renamed and must not be modified in any way, e.g. by saving. The Project proposal shall be delivered by data box (each separately) generated by the application without attachments, as a PDF file containing the Project proposal generated by the application.

(5) By submitting a Project proposal, the Applicant confirms that:

a) the Proposer is in an employment relationship with the Applicant or this relationship will be established no later than the date of the start of the Project;
b) at the time of submission of the Project proposal to the call for proposals, the Proposer has an academic degree of Ph.D., its equivalent or higher (e.g. CSc., Dr., DrSc., DSc., etc.), or will obtain it (in the case of Sub-program 2) no later than the date of conclusion of the Contract or the date of the Project Decision;
c) ensures that the Investigator fulfils all his/her obligations after the conclusion of the grant Contract or the Decision to increase the budget, in particular to be responsible for the professional level of the Project;
d) has familiarized himself with the Contract and undertakes to comply with its provisions;
e) he or she undertakes to comply after the conclusion of the Support Contract or the Decision of the budget increase, all the obligations of the Beneficiary arising from the law, the TD and the concluded Contract or the issued Decision;
f) all the information given in the Project proposal is true, complete and not distorted and is identical to the information entered in the Project proposal using the application, and that the Project proposal has been prepared in accordance with the TD;
g) all Co-applicants, the Proposer, Co-proposers and collaborators listed in the Project proposal have been informed of the substantive content of the Project proposal and of the financial requirements contained therein and of the TD;
h) before submitting the Project proposal, secure the consent of the above-mentioned persons to participate in the Project as described in the Project proposal;
i) for another Project with identical or similar issues has not accepted, is not accepting, and will not accept Support from another source;
j) the proposed scopes of work will allow the Applicant and Co-applicant to address all Projects in which they are involved;
k) agrees that the data provided in the Project proposal will be used for AZV's internal information system and published to the extent provided for by law and the TD;
l) in the event of the conclusion of a Contract for the provision of Support for the Project solution or the issuance of a Decision to increase the budget, the solution will be governed by the conditions for the solution set out in TD Annex 8;
m) where the Beneficiary or other Participant in the Project acts as a Research Organization, he or she will use the grant only for the non-economic activities specified in point 19 of the Framework.

(6) The Provider shall ensure that the information contained in the Project proposal is not made available to unauthorized persons. Any person authorized to have access to the contents of the Project proposal shall keep confidential any information which he/she has learned from it. These authorized persons are limited to the staff of the Ministry of Health and the AZV, members of the AZV's expert advisory bodies (the Office, the Scientific Council and the AZV's Supervisory Board), members of the expert advisory bodies (Evaluation Panels), the referees involved in the evaluation of Project proposals in this call for proposals, and any other experts involved in the

evaluation process. To this end, the Provider will ensure that they commit themselves to these obligations in writing.

(8) The Provider accepts only Project proposals with a confidentiality code S publicly available – complete and truthful Project data are not subject to protection under specific legislation. Project proposals with the confidentiality code U (the subject of the Project is classified information under special legislation or is information the disclosure of which could jeopardize the activities of the intelligence service) and C (the subject of the Project is subject to commercial secrecy (§504, §2985 of Act No. 89/2012 Coll., Civil Code, as amended) are not accepted for the public tender.

5.3. Project Proposal

(1) The duration of the Project in this call for tenders is 44 months (1 May 2024 – 31 December 2027).

(2) The Project proposal may be assigned to one of the Sub-program according to the stage of the Proposer's career path. In the ISVP application, these Sub-programs are distinguished as follows: '**VES 2024J**' for Junior Proposers and '**VES 2024**' for all others.

(3) **Project Description – the Justification of the Project Proposal** is to be completed in English. The file created outside the application shall be uploaded to the application in PDF format with a maximum size of 3 MB in a similar way to the Project proposal attachments. The maximum length of this section is 10 A4 pages, using a font size of 11 points and a line spacing of 1. The justification must clearly present the aims and objectives and provide sufficient information to assess the Project proposal, in accordance with the basic criteria for the evaluation of Project proposals. The **Project description must follow the following mandatory outline:**

a) **Introduction –** summary of the current state of knowledge of the scientific issues in the given field of science;
b) **Preliminary/pilot data –** pilot data supporting the Project focus and hypothesis (d);
c) **Statement of the Project Significance and its relevance to the Program;** justification of the necessity and need to address a specific scientific aim at a given time (i.e. the timeliness of the solution) and in a given scope; wherein lies the originality/innovativeness of the research Project;
d) **Hypothesis and objectives of the Project**;
e) **Experimental design –** statistical justification of the size of the research population (exceptions may be Projects aimed at research on rare and ultra-rare diseases), definition of groups and statistically justified numbers of experimental animals, numbers of repetitions in preclinical testing, etc.;
f) **Methodology –** description of the proposed conceptual and methodological approaches necessary for the Project and for achieving the expected result and their analysis, method of data acquisition, data analysis and proposed statistical analysis;
g) **Timetable –** a clearly formulated schedule of planned works and their scope in individual years of the solution; it is recommended to display the schedule using a Gantt chart;
h) **Expected results –** a factual description of the expected results of the Project, including their intended practical purpose and the aim of their use in healthcare;

i) **Cooperation –** please indicate if the Project solution is conditional on cooperation of several entities, how it will be implemented (model of future Contract as an Annex to the Project proposal), including specification of their share and responsibilities. In the case of foreign collaboration, a signed letter of support or letter of intent on the entity's letterhead should be provided, including the method and amount of funding; the Project solution should not be predominantly based on contracted research or paid services delivered by partners outside the Investigator Team;

j) **Information on the (personnel-wise and material-technical) readiness** of the Proposer, Co-proposers and their workplaces, on the technological equipment of the workplaces to be used in the solution, on the possibility of cooperation; promotion of gender equality principles within GEP, the HR Award, etc.; assessment of the consistency between the professional focus of the proposal and the focus of the Proposer/Co-proposers' workplace;

k) **Justification of the participation of** all Co-proposers and listed collaborators, definition of their contribution to the problem and specification of their role in achieving the expected results; information on the involvement of junior researchers;

l) **Risk analysis –** analysis of risks that may occur during the Project, their significance and impact, alternative solutions in case of failure to confirm the hypothesis, etc.;

m) A brief description of the **research data** that will be used, collected or generated during the Project and how it will be handled;

n) **List of literature used**.

These data may be supplemented by data based on the specific focus of the Project.

(4) The Project proposal is composed of forms after conversion:

- Part A – basic data, abstract;
- Part B – total funds, then total funds for individual Participants, breakdown of financial items justification of financial items;
- Part C – Bibliography (for the Proposer, Co-proposers);
- Part D – related Projects (Applicants, Co-applicants);
- Attachments;
- Statement.

(5) **Part A – Basic Data** includes:

a) Project registration number;

b) The Project start date (1 May 2024) and the duration of the Project in years (for reasons of use of the application, the duration of the Project in years will be rounded to 4 years for Project proposals with a Project duration of 44 months);

c) The title of the Project in Czech and English, in the wording intended must be specific, clear and concise, without abbreviated words and special symbols, and must not exceed 250 characters including spaces; the Project title must not be identical to another Ministry of Health Project proposal submitted by the same Applicant or to a Project already carried out with Support under the Act, on the basis of a comparison with the Research and Development Information System and innovation, part of the Central

Register of Research and Development Projects (hereinafter referred to as "**IS VaVaI – CEP**") made by the Applicant;

d) Designation of the relevant Evaluation Panel according to TD Annex 7; the Project proposal must be submitted to only one Evaluation Panel; if the Project proposal is interdisciplinary, another Evaluation Panel shall be selected, including justification;
e) Key terms in Czech and English;
f) Basic information about the Proposer and the Applicant, or Co-proposers and Co-contestants: name and surname, date of birth, ORCID ID, e-mail, telephone, organization, registered office, registration number; the inclusion of an incorrect registration number is a reason for the exclusion of the Project proposal from the public tender, even in cases of so-called clerical or numerical errors.

(6) **Part A – Abstract** states:

a) Inclusion of the Project in the discipline code OECD;
b) Designation of the relevant thematic sub-objective of the Program according to Article 3.3 of the TD;
c) An abstract in Czech and English, expressing the nature of the proposed Project and the specific results expected; the abstract, neither in Czech nor in English, must not exceed 2 000 characters including spaces and is intended for publication;
d) Project objectives in Czech and English (2000 characters); the Project objectives must not conflict with the objectives of the Program.

(7) **Part B – Total Funding** contains a proposal for the total eligible costs of the Project from all funding sources, broken down as follows for all Participants:

a) The total Provider subsidy for the Project, support from other public sources (domestic and foreign), support from non-public sources (own funds, private donations) and eligible costs from all funding sources for each year of the solution and the level of Support from the Provider;
b) The classification of the Project proposal into a specific category of research according to the Commission Regulation (basic research, industrial research, Development) according to the eligible costs and the share of the Project (if the Project cannot be clearly classified into a single category of research, the Applicant must specify the shares of each category of research in the Project according to the activities carried out, in accordance with the Regulation);
c) A breakdown of the recognized costs of the Project, broken down into other operating costs, investment costs, personnel costs, total eligible costs and special-purpose costs broken down by year of the Project.

(8) **Part B – Total Funds, Breakdown of Financial Items, Justification of Financial Items** shall be completed separately for the Applicant and for each Co-applicant. All financial resources shall be given as integer values in thousands of CZK.

Part B – Total Funding contains the total eligible costs of the Project from all sources of funding for the entire duration of the Project and in individual years, broken down into the funds requested from the Provider from the Special-purpose expenditure of the Ministry of Health, funds from other public sources (e.g. from institutional expenditure of the State budget for research,

development and innovation, from other sources of the State budget of the Czech Republic, from foreign public sources, including EC sources, etc.) and funds from non-public sources (e.g. own funds from private entities). A statement by the Applicant of the facts affecting the maximum Support intensity, the maximum Support intensity and the breakdown of the eligible costs of the Project is also provided. If the Project proposal foresees funding from different sources, the Project proposal must be accompanied by an affidavit of the sources of funding. The rate of Support corresponds to the proportion of the Support requested from the Provider from the Special-purpose expenditure of the MoH on the total Project costs; the Applicant's declaration of the facts affecting the maximum Support intensity.

(9) **Part B – Breakdown of Financial Items** is broken down as follows:

- Other operating costs:
  - material costs,
  - travel costs,
  - costs of other services and intangible costs,
  - additional (overhead) costs;
- Personnel costs:
  - wages of the Proposer and co-workers,
  - wages of administrative, technical and support staff,
  - other personnel costs,
  - social and health insurance, allocation to the FKSP or similar fund;
- The investment costs of the Project.

It shall also contain a **breakdown of the personnel costs for all years of the solution**, indicating the personnel costs and, where applicable, the financial remuneration for the work of the natural person – the Applicant or the Co-applicant according to Article 5.4.1 (6) from all funding sources in each year in the following breakdown:

a) Name, surname, job title or description of activities, working capacity (working time) and salary or wage as referred to in Article 5.4.1(2)(a) and (b) of the TD for the Proposer or Co-proposers and their professional collaborators or students, as appropriate;
b) The job description or description of activities, the aggregate working capacity (working time), the aggregate wage or salary referred to in Article 5.4.1(2)(a) and (b) of the TD for administrative, technical and support staff;
c) For other personnel costs for the payment of agreements for work outside the employment relationship in accordance with Article 5.4.1 (2)(c) of the TD; the name, surname, job title or description of activities, work capacity (number of hours) and amount for professional associates or students, or only the job title or description of activities, total work capacity (number of hours), total amount for administrative, technical and support staff;
d) Personnel costs – other (social and health insurance, FKSP, etc.).

(10) On the **Part B – Justification of Financial Items** form, the data is for the first year of the solution. In the event of a significant increase in the required costs in subsequent years of the solution under the relevant heading or in the event of the acquisition of tangible and intangible

fixed assets in subsequent years of the solution, their justification shall be provided in this Project proposal form. Each cost item, including costs from other sources, must be specified and justified, including an indication of the use to which it will be put, even where financing from other sources is proposed; in particular:

a) A detailed breakdown of material costs;
b) A justification of the amount of the travel fee, including the specific destination, person and purpose of the trip (e.g. active participation in conferences);
c) A detailed breakdown of other services and intangible costs;
d) A justification of additional (overhead) costs;
e) A detailed justification of personnel costs;
f) A specification of each item for the cost of acquisition of tangible fixed assets and intangible assets and its detailed justification according to Article 5.4.2. of the TD.

(11) **Part C – Bibliography of the Proposer and Co-proposers –** the Proposer and Co-proposers shall provide the following information:

a) **The five most significant results over their entire professional career** (e.g. journal publications, monographs, granted patents and other results of applied research); in the case of publications, the number of citations as determined by Web of Science [6] (WoS); in the case of scientific publications, the impact factor (IF) of the journal; the quartile or decile of the journal in the year of publication, or the last known one;
b) **Contribution to the field –** a verbal comment on the significance of the most important results achieved by the Proposer/Co-proposer and the most important contributions to the field ;
c) **List of research results for the last five years** (free form in PDF), for publication outputs the **author**'s **status (first, corresponding)**, IF of the journal (currently valid), quartile, decile according to WoS ;
d) **Total number of citations (excluding self-citations)** at the time of submission of the Grant Project according to WoS;
e) **H-index** according to WoS;
f) **History of international cooperation –** give specific examples of international cooperation, e.g. international grant projects**,** involvement in international consortia or joint research activities evidenced by joint publications;

(12) Part C shall include a **curriculum vitae of the Proposer and Co-proposer** to be completed in English. The file created outside the application shall be uploaded to the application in PDF format with a maximum size of 1 MB in a similar way to the Project proposal attachments. The maximum size is two A4 pages using a font size of 11-point, 1 line.

(13) **Part D – Information on Other Projects of the Proposer and Co-proposers Addressed with Legal Public Funding –** information is provided on all Projects addressed (running) with dedicated legal funding from all Providers, in the solution of which the Proposer or Co-proposers are involved at the time of submission of the Project proposal and in what role

[6] ISI Web of Knowledge (http://apps.webofknowledge.com)

(Proposer/Investigator, Co-proposer/Co-investigator, expert collaborator), as well as similar information on thematically similar completed (within the last three years) Projects of the Proposer or Co-proposer and thematically similar proposed applications for targeted Support submitted by the Proposer or Co-proposers. Each entry must include the following information about the Project about which information is being submitted:

a) The name of the body providing the funding (Provider);
b) The name of the program or other R&D activity (e.g. large infrastructure Projects, etc.), the Project number, the code characterizing the Project's classification according to the IS VaVaI– CEP, the unabbreviated title of the Project and the duration of the Project (from – to) for Projects or registration number, Evaluation Panel number, unabbreviated Project title and duration (from – to) for grant Projects;
c) The name of the Applicant/Beneficiary of the Special-purpose Support (of the Project/proposal);
d) The role of the Proposer, Co-proposer or team member in the Project/proposal;
e) The amount of Support expected/received for the entire duration of the Project that is/will be used by the Applicant or Co-applicant for its activities in the Project (i.e. the institution for which the Co-proposer has acted on the Project/proposal);
f) The working capacity of the Proposer, Co-proposer or team member to deal with individual Projects, even if the Support did/does not include salaries;
g) A description of the relationship of the Project on which the information is provided to the Project proposal submitted (in particular a description of the Project topic, objectives, results of the solution, Investigator collective, etc.).

If the Co/Proposer is not working on any Projects and has not submitted any proposals, he/she must confirm this in the ISVP.

(14) Only the following documents (depending on the nature of the Project) may be Annexes to the Project proposal:

a) Documents and affidavits to demonstrate eligibility in accordance with Article 4.2 of the Tender Documentation;
b) A list of experts who should **not** assess the Project (to ensure objectivity in the assessment of the Project – you have the option to list domestic and foreign experts who should not be involved in the Project assessment);
c) A bid identifying the supplier, the subject of supply and the provisional price and rate if the Project proposal specifies in detail the asset or service to be acquired as unique;
d) Proof of co-financing from other sources by an affidavit from the Applicant or a certificate from the intended sponsor;
e) Power of attorney to submit the proposal to a third party if the Applicant does not have its own data box;
f) The unsigned draft cooperation contract between the Applicant (Beneficiary) and the proposed other Participants; to be submitted whenever the Applicant is not the sole Participant in the Project proposal (i.e. whenever the Project is carried out in cooperation with the Applicant and Co-applicant(s));

g) The 'Motivational Effect' Annex – comparative analysis, comparison of the level of intended activity with and without Support, or comparison of the total amount spent by the Beneficiary on the Project with and without Support, or the rate of completion of the Project with and without Support, in case a large Enterprise is involved in the Project (see Article 5.6 of the TD);
h) If necessary, the original power of attorney (authorization) by which the Applicant's/Co-applicant's statutory body authorizes its representative to carry out acts related to the submission of the Project proposal.

5.4. Definition of Eligible Cost Items

(1) The Special-purpose Support may only be granted to cover costs directly related to the Project, which are included in the Project proposal and approved by the Provider as eligible costs in the Grant Contract/budget increase Decision.

(2) Eligible costs or expenses are only those defined by the provisions of Section 2 (2) (k) of the Act, which are specified in the TD in Article 5.4.1. to 5.4.3., and which are materially and temporally related to the Project.

(3) All items of eligible costs that are included in the Project proposal must be specified, justified, their necessity for the Project solution must be apparent from the Project proposal, they must be accountably demonstrable and efficiently usable.

(4) If the Applicant requests in the Project proposal the acquisition of a service or the acquisition of tangible or intangible assets in research, development and innovation, the Applicant shall in the Project proposal:

a) Specify and justify in detail the asset or service item to be acquired as unique (i.e., not substitutable by other similar assets or services) and at the same time necessary to meet the needs of the Project and provide evidence of the price and rate in effect at the time of the Project and supplier proposal by submitting a bid identifying the supplier, the item to be supplied, and the tentative price in accordance with Article 5.3(14)(c); or
b) Undertake to act as a Beneficiary in accordance with Act No. 134/2016 Coll., on public procurement, as amended.

(5) The supplier of the purchased assets or services must not be the Investigator or another employee of the Beneficiary or other Project Participant or a person connected (within the meaning of Section 23(7) of Act No. 586/1992 Coll., on Income Taxes) with the Beneficiary, other Project Participant, Investigator or member of the Investigator Team involved in the Project. Deliveries made in the form of in-house deliveries accounted for in accordance with generally binding legal provisions are acceptable.

(6) The Project proposal must indicate the proposed Support intensity. However, the final amount of eligible costs and the Support intensity of the eligible costs shall be decided by the Provider after evaluation of the Project proposal.

(7) Eligible costs cannot include, in particular:

a) value added tax (applicable to Beneficiaries who are liable for this tax and who claim a deduction or a pro rata deduction);

b) interest on debts;

c) shortages and damages;

d) other costs not directly related to the subject of the Project.

If the Project is accepted for Support, these costs are excluded from eligible costs for the entire duration of the Project, so they cannot be claimed as part of Project modifications.

5.4.1. Personnel Costs

(1) Includes mainly the personnel costs or expenses of the Applicant/Co-applicant's research and development staff, academics, students, technicians, laboratory technicians and other support staff, including those of the working professions involved in the Project. In the case of support staff, technicians, administrative staff (FTE, part-time or full-time), the Project proposal shall indicate only the activities they perform and the scope of these activities (not by name). The costs of compulsory statutory contributions and the allocation to the cultural and social fund (or other similar fund) or a pro rata share thereof (if such fund is not made up of profit allocations) may be claimed under personnel costs in an amount corresponding to the relevant wage bill.

(2) Amount of the personnel costs of the persons mentioned in the Project proposal and for the Project involved in the Project must correspond to the full-time equivalent of the Project. Zero staff capacity (full-time equivalent) is not allowed since the person concerned would then have no obligations (rights and obligations) in relation to the Project. **The Provider sets the minimum amount of registered (not converted) time per Project per employer for the Proposer/Co-proposer at 0,2 for the entire duration of the Grant.** In the event of an extension of the Project without eligibility for dedicated Support, proper completion of the Project, including submission of the final report in accordance with these tender documents, must be ensured in terms of staffing and funding. Personnel costs are only those costs incurred for the payment of wages and salaries in the context of labor relations under Act No 262/2006 Coll., the Labor Code, as amended (hereinafter referred to as the Labor Code). These are costs (only one of the above options can be used for a single worker):

a) for the wages and salaries, including variable components, compensation for sick leave and compensation for temporary incapacity for work (hereinafter referred to as "**wages**") of staff recruited under an employment Contract for the Project, where the sum of all full-time equivalents covered by the Provider's Grant may be no more than 100 % of the full-time equivalents of any one worker; or

b) for the relevant part of the wages of employees who are not recruited to the extent of the proportion of their working time involved in the implementation of the Project, whereby the sum of all the working time covered by the Provider's special-purpose Support may not exceed 100 % of the working time of any one employee; the overlap between part-time work covered by the Project's Special-purpose Support and the employee's working time in relation to the Applicant is accepted by the Provider, provided that the work is not equally defined; or

c) for the reimbursement of employment Contracts or agreements to carry out work outside the employment relationship concluded exclusively for the Project (does not apply to the person of the Investigator/Co-investigator).

(3) Under the Program, extraordinary remuneration (for personnel costs specified in points (a) and (b) of point (2) of Article 5.4.1 of the TD) may be paid from the Provider's funds (from the Special-purpose expenditure of the MoH) if the wages to which the extraordinary remuneration is related are paid from sources other than the Provider's Special-purpose Support and at the same time these other sources are indicated in the Project proposal. The total eligible costs of the Project will then be higher by these salaries than the costs covered by the Provider's special-purpose funding, even for Projects carried out exclusively by Research Organizations. It is not possible to list only exceptional remuneration, without salary (time), in the Project proposal. The Provider limits the amount of exceptional remuneration to a maximum of 100 000 CZK/employee/year for all Projects Supported by the Provider.

(4) The Applicant – an organizational unit, a contributory organization – shall proceed in accordance with 341/2017 Coll., on salary ratios of employees in public services and administration, as amended, and other relevant legal regulations.

(5) For researchers and students remunerated under paragraph (2) of this Article the Project proposal shall state the name of the researcher (the student should be identified in the application), as well as the job title, the working capacity (time) and the amount requested. For technical, auxiliary and administrative staff, only the total work capacity (full-time equivalent) planned shall be indicated for the year and the total amount requested.

(6) If the Applicant or Co-applicant is a natural person, the amount of his/her financial remuneration for work on the Project shall be included under the heading of personnel costs, even if it is not a cost incurred for the payment of wages and salaries in the context of labor relations under the Labor Code.

5.4.2. Acquisition Costs of Fixed and Tangible and Intangible Assets (Project Investment Costs)

(1) The costs of acquisition of tangible or intangible fixed assets that can be included among the eligible costs include only the acquisition of such tangible or intangible fixed assets that will be justified in detail in the Project proposal and whose necessity for the Project solution will be necessary.

(2) Eligible costs may include the acquisition of tangible and intangible fixed assets, the entry price of which is greater than or equal to the legal limit for the specific legal form of the Beneficiary and has an operational and technical function of more than one year.

(3) The cost of acquisition of tangible and intangible fixed assets of the Beneficiary or other Project Participants used in direct connection with the Project shall be determined as follows:

1. the amount of the recognized costs for the acquisition of assets under point (2), the operational and technical functions of which are longer than 1 year and at the same time longer than the duration of the Project, is determined according to the formula:

$$U_N = (A/B) \times C \times D$$

where U_N is the recognized cost, A is the period in years for which the asset will be used for the Project, B is the useful lifespan or operational technical function of the asset in years, determined according to special legislation, C is the acquisition cost of the asset determined according to special legislation, D is the proportion of use of the asset for the Project,

2. the amount of the recognized costs for the acquisition of assets under point (2), the operational and technical functions of which are longer than 1 year and at the same time equal to or shorter than the duration of the Project, is determined according to the formula:

$$U_N = C \times D$$

where the symbols U_N , C and D have the same meaning as in point 1,

3. the amount of recognized costs for the acquisition of tangible assets not listed in points 1 and 2 shall be determined according to the formula set out in point 2.

5.4.3. Other operating costs

(1) **Other operating costs** that may be included as eligible costs include material costs, travel costs, costs of other services and intangible costs and ancillary costs.

(2) **Material costs** are costs used exclusively in direct connection with the Project solution, which can be proven by a separate supplier's document or other objective way (e.g. by separate measurement), including material consumption (e.g. consumption of office and laboratory materials, acquisition of small material assets purchased or acquired by own activities within the Project solution, professional literature), energy consumption and other non-compoundable supplies.

(3) **Travel expenses** are costs covering all costs of business travel in accordance with the provisions of Sections 173 to 181 of the Labor Code, up to the amount provided for or permitted by this Act, for Investigators and other staff. These are costs incurred solely in direct connection with the Project, including working stays and travel in connection with **active participation in conferences**, where active participation in conferences is defined as a presentation in the form of a lecture or poster with an abstract in a professional journal or proceedings, where the author is named and the topic must be related to the Project. This also includes travel and subsistence expenses of foreign staff participating in the Project. The Provider will limit the travel costs to the maximum amount set for the Applicant and the Co-applicants combined:

- for the first year of the Project up to a maximum of CZK 80,000,
- in subsequent years of the Project up to a maximum of CZK 150,000.

(4) **Costs of other services and intangible costs** are costs used exclusively for the solution of the Project, which can be proven by a separate supplier's document or by other objective means, including costs for:

- operation, repair and maintenance of the assets used in the Project;
- the acquisition of small intangible assets as referred to in Article 5.4.2 (4), purchased or acquired by own activity within the framework of the Project;

- other services, e.g. contracts, publication costs (publication and editorial costs), including the cost of securing the rights to these results; publication costs for unrecognized results will not be accepted;
- conference fees;
- hire of premises, equipment and facilities for short-term events and activities with a scientific output (e.g. performing surgery, organizing a conference, holding a seminar);
- membership fees in institutions where membership is demonstrably necessary or economically advantageous to the Project;
- performance of connections;
- clinical and experimental studies (e.g. laboratory animals, specific administrative costs, administrative fees, costs of professional, ancillary and auditing services in the conduct of the clinical trial, costs of clinical evaluation insurance);
- other costs such as foreign exchange losses, bank charges, taxes and fees related exclusively to the Project;
- detailed and justified costs for the publication of the results (publication and editorial costs) in the form of books, articles, etc., in particular the organization in which the Applicant (or Co-applicant) plans to publish the publication. However, the publication of results (publication and editorial costs) through organizations which do not publish scientific and educational university literature (scripts, textbooks, etc.) **cannot be included** in the eligible costs.
- the costs of protection of the intellectual property created, as well as patent and royalty payments for the exercise of industrial property rights relating to industrial property objects (e.g. patents, inventions, industrial designs, royalties for the use of copyright) used in direct connection with the Project and necessary for its solution, and only for the period during which the industrial property rights are exercised for the Project solution (i.e. for the maximum duration of the Project solution). The amount of the eligible costs will:
    - where the period of exercise of the industrial property rights is longer than the period for which the rights will be used for the Project, the formula shall be:

      $$U_{(N)} = (A/B) \times C \times D,$$

      where $U_{(N)}$ is the eligible cost, A is the period of time during which the rights will be used for the Project solution, B is the period of operational and technical function (in accordance with Act No. 586/1992 Coll., on Income Taxes, as amended), C is the purchase price of the rights and D is the proportion of its use for the Project solution.
    - when the period of exercise of industrial property rights is equal to or shorter than the duration of the Project is determined from the formula:

      $$U_{(N)} = C \times D,$$

where the symbols $U_{(N)}$, C and D have the same meaning as in paragraph (6)(a) of this Article.

(5) **Ancillary (overhead) costs** are costs incurred in a direct temporal and material context in the implementation of the Project (e.g. administrative costs, support staff and infrastructure costs). The maximum amount of such costs is 20% of the Special-purpose Support requested from the MoH for all non-investment costs and expenses (other operating costs and personnel costs), i.e. excluding the cost of acquisition of fixed assets (Project investment costs). Such costs above this threshold cannot be eligible for targeted Support. The additional (overhead) costs planned in the Project proposal cannot be exceeded or requested to be increased in the course of the Project. If these costs are not requested in the Project proposal, they cannot be included as eligible costs.

5.5 Cooperation Between Enterprises and Research Organizations

(1) Effective collaboration on a Project between an Enterprise and a Research Organization in accordance with the Commission Regulation means their joint contribution to the Project design on the basis of a division of labor, their (joint) contribution to the implementation of the Project and their (joint) sharing of the risks and results of the Project.

(2) The terms and conditions of an effective cooperation Project, in particular as regards contributions to its costs, risk and result sharing, dissemination of results, access to intellectual property rights and rules for the allocation of such rights, should be established before the Project is launched[7]. Contract research and the provision of research services are not considered forms of collaboration.

(3) In order to be granted a premium for effective collaboration with a Research Organization, the conditions set out in Article 25(6) of the Commission Regulation (i.e. the required minimum share of the Research Organization in the eligible costs and the right of the Research Organization to publish the results of the research Project) must be met. The basis for assessing whether the Project proposal involves an effective collaboration between the Enterprise and the Research Organization will be a draft collaboration agreement between the Applicant (Beneficiary) and the proposed other Participants, which will show that the above conditions for an effective collaboration are met. This assessment will be made when evaluating the Project proposals.

5.6 Motivational Effect

(1) It shall apply to all Applicants and Co-applicants that the costs of the Project may not be incurred prior to the entry into force of the Grant Contract or the Decision to increase the budget. In order to meet the objectives of the Program and the conditions of the Commission Regulation, the Provider will assess the presence of the motivational effect of the Support under Article 6 of

[7] Does not apply to final agreements on the market value of the intellectual property rights created and the value of contributions to the Project

the Commission Regulation for all Applicants cumulatively for the whole Project as part of the evaluation process of Project proposals.

(2) In accordance with the Commission Regulation, the motivational effect of the Support is automatically demonstrated if the SME starts the Project after the entry into force of the Grant Contract and fulfils the conditions set out in the TD.

(3) Where the Applicant or Co-applicant is a large Enterprise, in order to meet the motivational effect in accordance with the Commission Regulation, the Project proposal must meet the requirements of Article 6(3) of the Commission Regulation, in particular to demonstrate that the Support will contribute to a significant increase in the scale of the Project or activity as a result of the Support, or will significantly increase the total amount spent by the Beneficiary on the Project or activity as a result of the Support, or will significantly accelerate the completion of the relevant Project or activity.

This motivational effect is demonstrated for a Project proposal where the Participant is a large Enterprise in a separate Annex (the model for this Annex is not prescribed, but the maximum extent is set out in two standard pages).

(4) The evaluation of the motivational effect will be part of the evaluation report prepared by the Provider's expert advisory body.

5.7. Expected Results

(1) The individual types of research, development and innovation (R&D&I) results are defined in a separate Annex 4 to the M17+ Methodology entitled Definition of Types of Results (approved by Government Resolution No.837 of 29 November 2017).

The main outcome is considered to be one of the following types of outcome:

- J_{imp} – peer-reviewed article – an original article in a peer-reviewed journal that is included in the Web of Science database with the "Article" flag[8]
- F – utility model, industrial design
- G – prototype, functional sample
- N – methodology, treatment procedure, specialized map with specialized content
- P – patent
- R – software
- Z – semi-operation, proven technology

A **secondary outcome** is one of the following types of outcome:

- J_{imp} – peer-reviewed article – an article in a peer-reviewed journal that is included in the Web of Science database with the "Review" or "Letter" flag
- J_{sc} – peer-reviewed article – an original/reviewed article in a peer-reviewed journal that is included in the SCOPUS database with the "Article", "Review", or "Letter" flag

[8] In the evaluation, the quality of the results will be judged primarily, not their quantity.

- B – professional book
- C – chapter in a professional book
- V – research report, summary research report

Further results are detailed in a separate Annex 4 of the M17+ Methodology.

For the purposes of this Program, a main, secondary and other R&D&I result is considered to be a new result that has been achieved within the framework of a Project Supported under this Program and has been claimed as a result of this Project in the register of information on IS R&D&I results.

For a successful solution, at least **one main and one secondary result** must be achieved. Alternatively, at least **two main results** or **one main result of the J_{imp} type published in a journal with an IF in the first quartile (Q1)** of the field according to WoS is also acceptable. For Projects requesting more than 12 million CZK in dedicated Support, at **least two main and one secondary result** will be required **(at least three main results** or **one main Jimp result published in a journal with an IF in the first decile (D1)** of the field according to WoS **is also acceptable)**.

Another general condition for successful Project solution is that at least one reported main result is of type J_{imp}, **which is dedicated only to the Project and to no other Project Supported by the Ministry of Health – AZV ČR**, where dedication means dedication in the publication output itself and also in the register of information on results of the R&D&I Information System. For the recognition of the main result, it is required that the Investigator is listed as an author or a member of the author's team.

(2) In the final evaluation of the Project, the **thematic focus of the results** will also be assessed, and only results that are in line with the Project's scientific aim are eligible.

(3) Successful Projects will be further evaluated mainly in terms of the quality of the results achieved and their contribution to the fulfilment of the Program objectives.

(4) As the Program Supports applied research Projects, beneficiaries will be obliged to attach a plan for the possible implementation of the results achieved into practice (i.e. an **implementation plan**) to the final Project report at the latest. These plans will serve the Provider as background material for future monitoring of the Projects' impact on practice.

(5) When publishing the Project results, it is recommended to carefully consider the choice of a peer-reviewed journal and **not to publish in dubious journals** that exhibit features of poor publishing practice, do not comply with publication standards and ethics (e.g. high number of self-citations, poor quality or fictitious peer-review procedures, fictitious names of editorial board members, fictitious quality indicators, etc.) (for more information, see for example https://openscience.cuni.cz/OSCIEN-36.html).

6. Method and Criteria for the Acceptance and Evaluation of Project Proposals

(1) In accepting and evaluating Project proposals, the provisions of Section 21 (1) to (9) of the Act shall be followed.

(2) The Project proposal cannot be changed or supplemented in any way after its submission to the public tender.

(3) The evaluation of the Project proposals shall start at the earliest on the day following the last day of the tendering period.

(4) The evaluation of Project proposals consists of (the process for evaluating Project proposals is described in TD Annex 9):

a) acceptance of Project proposals – is carried out in accordance with Section 21(2) of the Act; it follows immediately after the end of the tendering period and is concluded by the Decision of the Provider on the acceptance of Project proposals into the public tender or their elimination;
b) an assessment of the truthfulness, completeness and accuracy of the data in the Project proposals, which includes a check on the inconsistency of the data contained in the Project proposals, followed by following the Decision of the Provider to accept or reject the Project proposals and shall be carried out throughout the evaluation period;
c) evaluation of the professional level of Project proposals – the professional evaluation of Project proposals is carried out in accordance with Section 21 (5) to (7) of the Act; it follows the Decision of the Provider on the acceptance of Project proposals into the public tender or on their exclusion and ends with the preparation of Project proposal evaluation reports;
d) evaluation of proposed allowable and eligible costs – the relevance and correctness of proposed allowable and eligible costs in Project proposals is checked, in terms of the scope and definition of allowable and eligible costs and the amount of the proposed allowable and eligible costs; it follows the Decision of the Provider to accept the Project proposals in the call for proposals or to exclude them and ends with the preparation of the evaluation reports on the Project proposals.

(5) The evaluation of the Project proposals is completed with the announcement of the results of the public tender.

(6) The Decision to accept Project proposals in the public call for proposals or to exclude them 500/2004 Coll., Administrative Procedure Code, as amended, does not apply to the Decision of the Provider to select Projects for implementation within the meaning of Section 21 (11) of the Act.

6.1. Accepting Project proposals

(1) The acceptance of Project proposals is carried out by the Commission for the Acceptance of Project Proposals, which evaluates the fulfilment of the conditions of the call for proposals:

a) compliance with the tender deadline – it is assessed whether the Project proposal was submitted within the tender deadline;

b) the method and place of submission of the Project proposal – the assessment is whether the method of submission of the Project proposal specified in Article 8 of the TD, the name and originality of the file, the name of the ISDS batch[9];
c) completeness of the Project proposal – it is assessed whether the Project proposal contains all the specified parts according to Article 5.3 of the TD;
d) requirements for the demonstration of eligibility – the assessment is whether all supporting documents for the demonstration of eligibility have been submitted in the prescribed manner and whether these documents confirm the eligibility of the Applicant or Co-applicant;
e) Compliance with the minimum amount of time of the Investigator/Co-investigator according to the provisions of Article 5.4.1. (2).
f) compliance with the condition that the same natural person may act as Proposer and Co-proposer for only one Project proposal in this call for proposals.

(2) If it is proved that the Applicant or a Co-applicant has at any time during the tendering procedure become ineligible, this shall be grounds for the Project proposal to be excluded from the public tender.

(3) The Commission for the acceptance of Project proposals prepares a summary report on the evaluation of all received Project proposals, in accordance with Act No. 130/2002 Coll., and in the case of non-compliant Project proposals, states the reason for the exclusion from the expert evaluation of Project proposals.

6.2. Evaluation of the Truthfulness and Accuracy of Data in the Project Proposal

(1) The evaluation of the truthfulness and accuracy of the data in the Project proposal shall also aim at mutual inconsistency of data. The evaluation shall be carried out independently by the referees, Evaluation Panels, the Provider's expert advisory body, which is the Scientific Council of the AZV, and the staff of the AZV Office throughout the evaluation period.

(2) In particular, the following shall be deemed to be incorrect and false data:

a) The Project Description section of Article 5.3(3) of the TD is in a language other than the required language;
b) in Part A of the Project proposal in accordance with Article 5.3 (5) of the TD:
    1. an incorrect indication of the Applicant's or Co-applicants' ID number, whereby a deviation of the indication from the actual indication or the prescribed form, including so-called clerical and numerical errors, is considered an incorrect indication;
    2. an indication in a language other than the requested language,
c) in Part B of the Project proposal according to Article 5.3 (7) to (10) of the TD:

[9] Data box information system.

1. numerical data which are not in the prescribed currency or in the prescribed units;
2. the proposed Support intensity does not correspond to the actual proportion of the funds requested from the Provider in the total Project cost;
3. the proposed funding is contrary to applicable law;
4. the proposed personnel costs do not correspond to the relevant staff capacities (full-time equivalents) or do not adequately respect the provisions in Article 5.4.1;
5. the proposed costs are not specified in detail in Part B – Justification of financial items as per Article 5.3 (10) of the TD,

d) Part D of the Project proposal under Article 5.3(13) of the TD does not provide full information on other Projects of the Applicant and Co-applicant,

e) in all parts of the Project design:
   1. adopted texts not supported by a bibliographic citation in accordance with Article 5.2(1) of the TD;
   2. information that is untrue or does not correspond to reality.

(3) In particular, the following shall be considered contradictory data:

a) the difference in meaning between the title, keywords and abstract of the Project proposal in Czech and English;

b) the difference between the solution time in Part A of the Project proposal and the time resulting from Part B of the Project proposal and the Project Description.

(4) **The evaluation of the scientific quality of Project proposals** is carried out by the Provider's expert advisory body – the **AZV Scientific Council** and its expert bodies, which are the **AZV Evaluation Panels**. The quality of the Proposer, Co-proposers and the composition of the Investigator Team, the quality of the Project and the history of cooperation with the Provider are assessed in the evaluation of proposals.

(5) **For the quality of the Proposer, Co-proposers and the composition of the Investigator Team, the following** is assessed in particular:

The ability and aptitude of the Proposer, possible Co-proposer and their collaborators to deal with the Project, their professional skills, their overall contribution to the field of science are assessed, taking into account their previous results in research and Development, the extent of their active research activities over the last five years (i.e. Their role as first or corresponding author); the expertise of the team needed to address all Project objectives; the involvement of junior researchers; the history of international collaboration; the technical and institutional background of the Applicant and Co-applicants; the integration of gender aspects of the Investigator Team (e.g. gender equality plan, gender equality measures as part of the HR Award, etc.) shall also be taken into account.

(6) For the **quality of the Project**, the following is assessed:

a) **project focus and relevance –** the Project focus is assessed in terms of whether it is in line with the areas of Support given by the Program, originality and topicality of the topic addressed, expected benefits, their feasibility and potential impact,

b) **quality of the Project design –** quality of the scientific hypothesis, definition of the research objectives of the Project and their consistency with the hypothesis, quality of the pilot data, their relevance to the thematic focus of the Project and the formulated hypothesis; quality of the experimental design, statistical justification of the composition and size of the research population (an exception may be Projects focused on research on rare and ultra-rare diseases), definition and statistical justification of the number of experimental animals, sufficient numbers of replicates in preclinical testing, etc. adequacy and timeliness of the planned methodological approaches, their suitability for meeting the research objectives; formal quality of the Project proposal, precision of wording, quality of technical language, number of typos, etc.,

c) **feasibility and other aspects of the Project –** feasibility of the study and timetable; sophistication of risk analysis; pure validation studies or Projects whose solutions are predominantly based on contracted research or paid services delivered by partners outside the Investigator Team will not be preferred for Support.

(7) **Previous cooperation with the Provider –** the results and methods of the Applicant's (and Co-applicants') and Proposer's (and Co-proposers') Projects in dealing with Projects with Support provided by the Provider (if such Projects have been dealt with by the Applicant); any breaches of the rules by the Applicant (and Co-applicants) or the Proposer and Co-proposers) in the management of the Special-purpose Support provided, the fulfilment of all the obligations defined in the Contract for the provision of dedicated Support/ Decision on the budget increase, the evaluation of Projects already completed or currently under way.

6.3. Economic Evaluation of Project Proposals

(1) The economic evaluation of Project proposals shall be carried out objectively and impartially throughout the evaluation.

(2) In assessing the proposed eligible costs, the following shall be considered:

a) the reasonableness of the proposed eligible costs in relation to the Project proposal and the expected results;
b) the level of specification and justification of the individual items of recognized costs;
c) the proportion of the funds requested from the Provider in the total proposed eligible costs (i.e. the proposed Support intensity);
d) compliance with the requirements for the scope and definition of eligible costs under Article 5.3(7) to (10) and Article 5.4 of the TD.

(3) The Provider's expert advisory body may propose that the Provider should not recognize part of the costs/expenses proposed by the Applicant for the Project and not include them among the recognized costs of the Project on the basis of the Act. The Applicant will be informed of this procedure by email and asked whether he/she will be able to carry out the Project with the reduced

financial Support. If the Applicant refuses, the Project is classified as unsupported. If they agree, they will be asked to provide a corrected budget.

6.4. Reasons for Eliminating a Project Proposal from the Public Tender

(1) Any violation or non-compliance with the conditions defined in the TD shall be grounds for the exclusion of the Project proposal from the tender pursuant to paragraph 21(3) of the Act, and explicitly the conditions specified in Article 2.3(1); Article 3.3(3) and (4); Article 4.2. paragraph (1), (2),(4) to (6); Article 5.1. paragraph (2); Article 5.2. paragraph (1) to (5); Article 5.3. paragraph (3),(5) to (13); Article 5.4.1, paragraphs (1) to (6); Article 5.6, paragraphs (1) to (3); Article 6.1, paragraphs (1) and (2); Article 6.2, paragraphs (2) and (3); and Article 8.

(2) Submission of a Project proposal that has already received Special-purpose Support under the Act or that is submitted as a duplicate or multiple times in a given calendar year to any providers' public tenders shall be grounds for elimination of the Project proposal from the public tender.

(3) The reason for the exclusion of a Project proposal from the public tender pursuant to Section 21 (3) of the Act is the fact that the Beneficiary in previous Projects has demonstrably failed to comply with the obligations laid down in the Financial Regulation Act or has breached obligations arising from the Contract or the terms of the Decision. In this case, the MoH may exclude the Beneficiary's Project proposals from the public tender for a period of up to three years from the date on which the Beneficiary has been proven to have committed such a breach or has acknowledged it in writing.

(4) The fact that a Project is submitted by an Investigator whose Project financed from the Special-purpose Support of the Ministry of Health has been prematurely terminated due to failure to fulfil the obligations set out in the Project Contract is also a reason for the Project proposal to be excluded. This concerns Projects that have been stopped in the last 3 years.

(5) A Project Investigator whose final report has been evaluated in the "S" category is not awarded a dedicated MoH Grant for the following 3 years (from the date of this evaluation, not from the end of the Project) and is therefore excluded from participation in further MoH public tenders for this period.

7. Definition of Data to be Disclosed

(1) For the purposes of the tender and the fulfilment of the other obligations of the Provider the Provider is entitled to collect the necessary data on Project proposals and Applicants (Co-applicants), including personal data, for the purposes of Section 17(6) of the Act and for the fulfilment of its obligations under Section 32 of the Act. Both written and electronic forms of data collection are allowed. These data are not publicly available information.

(2) In collecting, processing and disclosing data, the Provider shall be governed by specific legislation[10]. The scope of the data processed on Project proposals and Applicants is shown in The Project proposal data are identical to the data that the Beneficiary is obliged to submit to the IS VaVaI – CEP.

(3) When announcing the results of the public tender, only the data on the Projects which the Provider has decided to accept for solution shall be published, in the following scope: designation of the Beneficiary; name, surname, academic titles and scientific ranks of the Investigator; title of the Project; title of the Program; Program code; application number; duration of the Project.

(4) Following the conclusion of a Contract for the provision of special-purpose Support or the issuance of a Decision to increase the budget for the Project, the data pursuant to the provisions of Sections 30 to 32 of the Act shall be published;

(5) After the completion of the Projects and their evaluation, the scientific parts of the Projects (extracts from the final reports) will be submitted to the National Library of Medicine for electronic archiving. This information will then be publicly available.

8. How to Submit Proposals

(1) The Project proposal shall be submitted in electronic form in accordance with Article 5.2(4) of the TD. The identifier of the AZV data box where Project proposals will be delivered is "**f7eike4**". Delivery via the data box will be marked in the 'Subject' field with the text '**AZV – NW24-XX-00XXX**' or '**AZV – NW24J-XX-00XXX**' (the relevant Project proposal numbers generated by the ISVP application will replace 'X').

(2) It is forbidden to modify the PDF file containing the Project proposal in any way and may only be delivered in the form in which it was created by the application and in accordance with the procedure described in Article 5.2 (4) of the TD.

(3) The affidavits to demonstrate eligibility are included in the TD as Annex 2-5 or are available on the websites of the Provider and AZV.

(4) **The affidavits referred to in Annexes 2-5 of the TD and other documents** referred to in Article 4.2 (1) and Article 3.2. (3) of the TD shall be **delivered during the tender period in paper form by post or in person to the AZV ČR mailroom at Ruská 2412/85, 100 00 Prague 10 in an envelope marked "DO NOT OPEN – VES 2024" or signed with a qualified electronic signature in accordance with a special legal regulation[11] to the AZV data box.** The original power of attorney (authorization), if applicable, by which the Applicant's/Co-applicant's statutory body authorizes its representative to carry out acts related to the submission of the Project proposal, will be delivered in the same way. **All other attachments required by the TD shall be submitted**

[10] Act No. 110/2019 Coll., the Personal Data Processing Act, as amended, and Regulation (EU) 2016/679/EC of the European Parliament and of the Council on the protection of natural persons with regard to on the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) ("GDPR").

[11] Act No. 297/2016 Coll. on Trust Services for Electronic Transactions.

through the ISVP application as an embedded attachment in PDF format. In the case of a power of attorney to submit a proposal to a third party, if the Applicant does not have its own data box, the Applicant shall attach the power of attorney as an Annex in the ISVP application and deliver it in paper form by post or in person to the address of the AZV ČR, Ruská 2412/85, 100 00 Prague 10 in an envelope marked "DO NOT OPEN – VES 2024"

(5) The Project proposal and the Annexes, which are to be submitted in written form, may be submitted in accordance with the procedure laid down no earlier than the first day of the tender period and no later than the last day of the tender period, which is set out in Article 2.1(2) of the TD. The date and time of delivery to AZV's data box, the date of submission to the Czech Post or the date of delivery in the case of personal delivery or use of another delivery service are decisive for the assessment of compliance with the deadline for submission.

Attachments

Annex 1 – Model Support Contract

Annex 2 – Model Affidavit of Eligibility

Annex 3 – Affidavit as per Financial Regulation

Annex 4 – Affidavit for Research Organizations

Annex 5 – Sample Affidavit for Proving the Eligibility of an Applicant/Co-Applicant Based Outside the Czech Republic

Annex 6 – Opinions on the Project Proposal

Annex 7 – Distribution of Evaluation Panels According to Their Expertise

Annex 8 – Project Terms and Conditions

Annex 9 – Project Proposal Evaluation Process

Annex 1 – Model Support Contract

Contract for the Provision of Special-purpose Support for the Project No NU24(J)-xx-xxxxxxx Panel No PXX

In Tender no.1 in Research, Experimental Development and Innovation announced under the Applied Health Research Support Program for 2024 – 2026 (hereinafter referred to as "**Public Tender**") pursuant to Act 130/2002 Coll., on the Support of Research, Experimental Development and Innovation from Public Funds and on Amendments to Certain Related Acts (the Act on Support of Research, Experimental Development and Innovation), as amended (the **Act**) and Act No. 89/2012 Coll, Civil Code, as amended, and Act No. 218/2000 Coll., on Budget Rules and on Amendments to Certain Related Acts (Budget Rules), as amended.

Pages

a) Czech Republic – Ministry of Health

375/4 Palackého nám. 128 01,

Prague 2

ID: **00024341**

Represented by: **prof. MUDr. Vlastimil Válek, CSc., MBA, EBIR, Minister**

(hereinafter referred to as "**Provider**")

b) xxxxxxx

Address: xxxxx

ID: xxxxxxx

Represented by:
.....

Registered:
.....

Account No.:..... /current ..... with

(hereinafter referred to as **"Beneficiary"**)

have concluded today this

Contract for the Provision of Special-purpose Support for the Project No NU24(J)-xx-xxxxxxx Panel No PXX

in the Tender no.1 in Research, Experimental Development and Innovation announced under the Program for the Support of medical applied research for the years 2024-2030 (hereinafter referred to as the **"Contract"**):

I. Project

1. On 16 May 2023, the Provider launched a Public Tender. The Beneficiary submitted a Project proposal to the Public Tender, which was assigned the registration number NU24(J)-xx-xxxxx by the Provider and which forms an integral part of this Contract. The Project proposal is placed in the Project proposal and management application (hereinafter referred to as the **"Application"**) for its scope, where it can be viewed at any time by the Project Investigator (hereinafter referred to as the **"Project Proposal"**) in the Application under the name MZ VES 2024.
2. Project name: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
3. Subject and objectives of the Project: xxxxxxxxxxxxxxxxxx.

   The objectives of the Project, its expected results and the means of verifying their achievement are precisely and bindingly stated in the Project Proposal.

   Project registration number: NU24(J)-xx-xxxxxxx

   (hereinafter referred to as **the "Project**")
4. Project start date: 1 May 2024

Project completion date: 31 December 2027

Date of delivery of the partial report: always no later than 15 January of the calendar year immediately following the relevant Project year

Date of delivery of the final report: by 31 January of the calendar year following the completion of the Project.

5. The Investigator (including all academic titles and academic ranks, if any): xxxxxxxxxxxxx

   (hereinafter referred to as the "**Investigator**").

6. Level of confidentiality of data according to the provisions of generally binding legal regulations: S – publicly accessible.

II. Total Cost of the Project

1. The total amount of eligible costs (according to Section 2(2)(n) of the Act) for the entire duration of the Project is specified in the Project Proposal in Form Part B – in accordance with Article 5.3(7) of the Tender Documentation.
2. The total amount of Special-purpose Support from public funds provided by the Provider (hereinafter referred to as "**Special-purpose Support**") for the entire duration of the Project is **CZK** xxxxxx.
3. For each year of the Project, the amount of the Special-purpose Support from public funds provided by the Provider is:

Year	Amount
2024	**xxxxxx CZK**
2025	**xxxxxx CZK**
2026	**xxxxxx CZK**
2027	**xxxxxx CZK**
Total	**xxxxxx CZK**

4. The breakdown of the Special-purpose Support for each year of the Project is set out in Annex 1, which forms part of this Contract.

III. Basic Provisions

1. On 16 May 2024, the Provider announced a Public Tender, and the rights and obligations of the Provider and the Beneficiary as an Applicant during this Public Tender were, in addition to generally binding legal regulations, regulated by the Tender Documentation for this Public Tender (hereinafter referred to as **the "Tender Documentation"**). To the extent that the Tender Documentation is relevant to the performance of this Contract, the Beneficiary is obliged to comply with it **in the performance of this Contract**. The Beneficiary shall also oblige the Investigator and the other Participant (who shall oblige the Co-investigator) to do so. In the event of any conflict between the provisions of this Contract and the TD, the provisions of this Contract shall prevail. The TD is available on the websites of the Provider (www.mzcr.cz) and the AZV, an organizational unit of the State (www.azvcr.cz). The Beneficiary has submitted a Project Proposal to this Call for Proposals.
2. Based on the results of the Public Tender, the Provider concludes this Contract with the Beneficiary in order to regulate mutual rights and obligations in providing Support from public funds for the Project, the specification of which is set out in Article I of this Contract and in the Project Proposal.

IV. Investigator

1. The Investigator identified in Article I.5 of this Contract is responsible to the Beneficiary for the professional level of the Project. The rights and obligations of the Investigator in relation to the Beneficiary shall be governed by a separate Contractual relationship between them unless the Beneficiary is also the Investigator. The rights and obligations of the Investigator vis-à-vis the Provider shall be governed by the provisions of this Contract and the TD.
2. The Beneficiary is responsible for the fact that the Investigator has been informed about the content of this Contract, including all its Annexes and amendments, as well as the TD and that he undertakes to comply with all provisions of generally binding legal regulations, the Contract, including all its Annexes and amendments, and

the TD in relation to the Provider.

3. The Beneficiary hereby assures the Provider that the above-mentioned Investigator is and will be in an employment relationship with the Beneficiary for the entire duration of this Contract on the basis of an employment Contract unless the Beneficiary – natural person is also the Investigator.

V. Recognized Costs and Public Support

1. The Provider has approved as eligible costs those costs that are listed in the Project Proposal (including any reduction in the total amount of Special-purpose Support requested). By signing this Contract, the Beneficiary declares that it accepts these changes, if any.
2. The detailed specification of the items of eligible costs and their breakdown is set out in the Project Proposal, in Annex 1 – Schedule of eligible costs and Special-purpose Support for each year of the Project.
3. The total amount of the Special-purpose Support is set out in Article II(2) of this Contract.
4. The amount and distribution of public Support is set out for each year of the Project in Article II(3) of this Contract.

VI. Provision of Special-purpose Support

1. For each year of the Project, the Provider shall provide the Beneficiary with the Special-purpose Support for the Project in the amount specified in Article II, paragraph 3 of this Contract, subject to the conditions, within the time limit and in the manner resulting from the provisions of the TD and this Contract.
2. If, as a result of the budget provisional period, the budget spending is regulated, the Provider is entitled to set a deadline for the provision of the Special-purpose Support to the Beneficiary by written notification. The Provider shall also always be entitled to withdraw from this Contract in the event of a budgetary adjustment as a result of the budget provisions.

VII. Participation of Other Participants

1. If one or more other Participants are to be involved in the Project, the participation of the other Participants as well as the scope and specification of the participation of each other Participant in the Project shall be specified in the Project Proposal. The amount of their Support for each year of the Project is set out in Annex 1 – Schedule of Recognized Costs and Special-purpose Support for each year of the Project.
2. If one or more other Participants are to participate in the Project, the Beneficiary is obliged to conclude a written Contract on participation in the Project with each other Participant within the time limit, under the terms and conditions and with the particulars according to the TD and this Contract, and to deliver one copy **of** each such Contract together with all attachments to the Provider at its registered office within this time limit. The Project Participation Contract shall be concluded between the Beneficiary and the other Participant for a definite period of time, at least for the period for which this Contract is concluded between the Beneficiary and the Provider.
3. If the Provider provides Support to the Beneficiary including the part of the Support intended for the other Participant, the content of each Project Participation Contract concluded between the Beneficiary and the other Participant must include a provision that the Beneficiary will provide the other Participant with the part of the Support intended for him/her within 30 days of the Beneficiary's receipt of this part of the Support from the Provider, by transfer to the account of the other Participant held with a financial institution, which must be explicitly stated in the Project Participation Contract. The Beneficiary is obliged to provide the other Participant within the specified period and in the specified manner with all the funds constituting the part of the Support intended for the other Participants and at its disposal.
4. The Beneficiary is obliged to make part of the content of each Project Participation Contract concluded with another Participant a provision binding the other Participant to comply with all obligations of the Beneficiary as well as the obligations of the other Participant arising from the provisions of this Contract and the provisions of the Contract, except for the provisions whose nature implies that they cannot apply to the other Participant.
5. The Beneficiary is obliged to make part of the content of each Project Participation Contract concluded with the other Participant a provision obliging the other Participant to enable the performance of control over the fulfilment of its obligations to the extent and in the manner resulting from this Contract, from the provisions of the Contract, as well as resulting from the provisions of the Project Participation Contract concluded between the Beneficiary and the other Participant and generally binding legal regulations, both for the Beneficiary and the Provider (the control rights of the Beneficiary and the Provider towards the other Participant are thus identical). Furthermore, the Beneficiary is obliged to make part of the content of each Project Participation Contract concluded with another Participant a provision obliging the other Participant to fulfil the obligations contained in the TD both

towards the Provider and the Beneficiary.

6. The Project Participation Contract must also include the name, surname (including any academic titles and academic ranks) and date of birth of the other Participant appointed by the Co-investigator.

VIII. Use and Management of Special-purpose Support

1. The Beneficiary acknowledges that any funds provided to it by the Provider under this Contract are subsidies under generally binding legal regulations and are Special-purpose. The Beneficiary or other Participant shall use such funds exclusively to reimburse the Project's eligible costs under this Contract incurred by the Beneficiary or other Participant in addressing the Project under the terms and to the extent resulting from this Contract, the TD and generally binding legal regulations.
2. The Beneficiary is obliged to manage the provided Special-purpose Support with due care and diligence, to comply with the obligations set out in this Contract, the Tender Documentation and generally binding legal regulations (in particular Act No. 218/2000 Coll., on Budgetary Rules and on Amendments to Certain Related Acts (Budgetary Rules), as amended), and is further obliged to follow the Provider's written instructions when managing the provided Special-purpose Support, without undue delay after receiving them. The Beneficiary shall furthermore oblige any other Participant in a similar manner.
3. If during the course of the Project any facts arise requiring any change in the composition or amount of the Special-purpose Support, the procedure shall be as specified in the TD for changes within the Project.
4. The use of the Special-purpose Support and the principles of their management are further governed by the provisions of the GC and generally binding legal regulations.
5. If the Beneficiary or any other Participant violates any obligation related to the management or use of the Special-purpose Support arising from the provisions of generally binding legal regulations or this Contract or the Contracts, the Provider is always entitled to withdraw from this Contract. This is without prejudice to other consequences of the breach of an obligation arising from generally binding legal regulations, this Contract or the Contract.

IX. Recording and Settlement of Support Granted

1. The Beneficiary is obliged to keep separate accounting records for the Project (in accordance with generally binding legal regulations governing the keeping of accounting records), which must be kept correctly, completely, conclusively, clearly, in a manner guaranteeing the permanence of accounting records, and in such a way that the Beneficiary can provide credible, up-to-date and verifiable data on the state of management of the Special-purpose Support at any time upon the Provider's request and also prove these data.
2. A separate and distinct record of all recognized costs must be kept in a separate analytical account within the above accounting records, and a separate and distinct record of expenditure and costs paid from the Special-purpose Support must be kept within the above accounting records. The records of the management of the Special-purpose Support must therefore be kept completely separate from the records of any other funds spent on the Project (e.g. funds of the Beneficiary or another Participant). For each result claimed, the Beneficiary must declare all sources of public funds with whose Support the result was achieved.
3. The Beneficiary shall keep the documents on the Project financed from the Special-purpose Support for at least ten years after the termination of this Contract.
4. For each calendar year of the Project, the Beneficiary is obliged to submit, on the basis of its own and another Participant's accounting records, an accounting of the Special-purpose Support spent on the Project as of the date set by the Provider. At the same time, it shall submit an account of the eligible costs of the Project, indicating all sources of their coverage. The Recognized Costs of the R & D Projects are defined by the Act, the TD and this Contract.
5. If the accounting in the separate analytical records kept for a given Project in a given calendar year (and it is not the last year of the Project) ends with a surplus, i.e. all funds provided to the Beneficiary or another Participant for the respective year are not used, the Beneficiary is obliged to inform the Provider about this fact. Unused Special-purpose Support from a given calendar year (unless they are transferred to the Special-purpose Support fund by eligible entities – see Section 26 of Act No. 341/2005 Coll., on Public Research Institutions, as amended, and Section 18 of Act No. 111/1998 Coll., on Universities, as amended) may be used by the Beneficiary or another Participant in subsequent years of the Project in accordance with the approved Project Proposal, i.e. for the same purpose for which they were approved by the Provider. Changes in the purpose of use of unspent Special-purpose Support are possible within the scope defined by the TD. At the same time, it is necessary to comply with all the limits set by the TD for a given calendar year. If the Beneficiary (and for the next Participant) is not interested in

using the unspent Special-purpose Support in the following years of the Project, it shall inform the Provider and return the unspent funds according to the Provider's instructions.

6. Upon completion of the Project, the Beneficiary (and any other Participant) is obliged to return all unspent Special-purpose Support from the Project to the State budget. The conditions for financial settlement of the Special-purpose Support provided shall be determined by the Provider in accordance with the legal regulations
7. Other obligations of the Beneficiary regarding the keeping of accounting records arise from the TD and generally binding legal regulations.

X. Controls

1. The Provider is entitled to carry out at any time control and evaluation of the fulfilment of the Project objectives, including control of the drawdown and use of the Support and management of the Special-purpose Support, the effectiveness of the costs recognized under this Contract, the use of the Project results and the fulfilment of the obligations of the Beneficiary, the Investigator, the other Participant and the Co-investigator, both for the Beneficiary and the other Participant.
2. The Beneficiary (as well as the Investigator) and the other Participant (as well as the Co-investigator) is obliged to allow the Provider to exercise its control rights under this Contract and the TD and to provide the Provider with all necessary or requested cooperation. The Beneficiary shall oblige each additional Participant to submit to the Provider's control to the extent specified in this Article X. and the additional Participant shall similarly oblige each Co-investigator appointed by it.
3. The Provider has the right to carry out an inspection according to this Contract or the TD at any time during the Project as well as after its completion. An inspection by the Provider at the Beneficiary or at another Participant does not replace in any way the inspection by the territorial financial authorities according to generally binding legal regulations.
4. The Beneficiary is obliged to provide only true, complete and undistorted information in the partial reports, the final report or any other documents (notifications, requests, information, etc.) delivered to the Provider. If the Beneficiary breaches this obligation, the Provider shall always be entitled to withdraw from this Contract, without prejudice to the other obligations of the Beneficiary provided for in this case by generally binding legal regulations, this Contract or the TD.
5. Other rights and obligations of the parties regarding the control result from the provisions of the Contract.

XI. Project Solution Procedure

1. The Beneficiary is obliged to start the Project within 60 calendar days from the effective date of this Contract, in case of a budgetary provision within the time limit and in accordance with the procedure under Act No. 218/2000 Coll. on budgetary rules and on amendments to certain related acts (budgetary rules), as amended, and to continue the Project until the date of completion of the Project as specified in Article I, paragraph 4 of this Contract or until the termination of the effectiveness of this Contract, if earlier, in the manner resulting from this Contract, in particular from its Annexes, the TD and generally binding legal regulations.
2. The Beneficiary and the other Participant are obliged to proceed with the Project with professional care, using all the expertise of the Beneficiary, the Investigator, the other Participant and the Co-investigator. The Beneficiary shall oblige each other Participant to proceed with the Project as described in the preceding sentence.
3. The Beneficiary and other Participants are obliged to use the tangible and intangible assets acquired by the Beneficiary from the Special-purpose Vehicle for the Project within the scope and in the manner resulting from this Agreement or the Contract. The Beneficiary shall oblige each other Participant in the manner set out in the preceding sentence.
4. As part of the Project implementation process, the Beneficiary is obliged to submit to the Provider partial reports and the final report within the timeframe, in the manner and with the formalities according to the TD and this Contract.
5. The Beneficiary undertakes to comply with other obligations arising from the provisions of the LDS and generally binding legal regulations in the course of the Project.
6. The Beneficiary shall be obliged to complete the Project no later than the date of completion of the Project specified in Article I, paragraph 4 of this Contract and to document or present the results of the Project to the Provider in accordance with the Project Proposal and the relevant provisions of the Contract.

XII. Evaluation of the Beneficiary's progress in solving the Project

1. On the basis of the results of the Provider's control activities and partial reports, the Provider carries out a regular annual evaluation of the Beneficiary's progress in the implementation of the Project, in the manner and according to the criteria specified in the TD.
2. In the event of any breach of obligations by the Beneficiary or irregularities arising from the Project solution or partial report, the Provider, in addition to applying sanctions under this Contract, is entitled to specify the amount of Support for the next years of the solution in the form of an amendment to this Contract, in accordance with the procedure, time limit and under the conditions according to TD.
3. If, at the Provider's discretion, the prerequisites for the continuation of Support for the Project are not met, or if the Beneficiary has rejected the draft amendment to this Contract, the Provider is always entitled to withdraw from this Contract.

XIII. Evaluation of the Results of the Completed Project

1. When publishing the results of the Project, the Beneficiary (Author/Investigator/Co-investigator/Expert Collaborator) is obliged to indicate that the Project was carried out with the Provider's Support.
2. The method and criteria for the evaluation of the completed Project are specified in the TD or on the Provider's website. The evaluation of the completed Project is carried out by the Provider on the basis of the assessment by the evaluation bodies mentioned in the TD, on the basis of the final report and the result of the audit activity on the management of the granted special-purpose Support. In the overall evaluation of the completed Project, the Provider shall also take into account compliance with the conditions of management of the Special-purpose Support granted. Each Project is evaluated separately.
3. During the final evaluation of Projects after the completion of their solution in accordance with § 13 (4) of the Act, the Provider shall evaluate the achievement of the objectives set out in the Contract, the results achieved by the Project, their relationship to the Project objectives and provide data on them in the information system for research, experimental development and innovation in accordance with Government Regulation No.397/2009 Coll., on the information system for research, experimental development and innovation.
4. The results of the evaluation of completed Projects are published by the Provider on its website for the year in aggregate.
5. The Provider shall carry out a final evaluation of the Project in the calendar year following the completion of the Project. The Provider determines the basic categories of the final evaluation of the Project result, which will be submitted in the form of a final report as follows: V = excellent Project results (with international importance, etc.), which means that the Project objectives and its expected results as specified in the Contract for granting Support have been met, U = succeeded according to the assignment, i.e. U = Project objectives and expected results as stated in the Grant Contract were met; O = Project did not meet the terms of reference, but the Contract was complied with; S = Project did not meet the terms of reference, the penalty provisions of the Contract were complied with.

XIV. Information System for Research, Experimental Development and Innovation

1. The Beneficiary is obliged to process data for the Information System for Research, Experimental Development and Innovations (IS VaVaI), part of the Register of Information on Results (RIV) and deliver these data to the Provider to the extent resulting from generally binding legal regulations. The Beneficiary is obliged to deliver to the Provider, by the deadline announced annually by the Provider, data on the results of all its Projects carried out with the Provider's Support, which are intended for the IS VaVaI, RIV in accordance with the Act and Government Regulation No. 397/2009 Coll., on the Information System for Research, Experimental Development and Innovation. In the event that it is necessary, according to the Project design, to document an output, for example a publication or a part thereof, to fulfil the above requirement, the Beneficiary shall do so without delay within the set deadline. In case the output of the solution shows that it is necessary to provide both electronic and written forms for compliance, the Beneficiary is obliged to provide both forms to the Provider.
2. The Beneficiary is obliged to check at least once a year for a period of 5 years from the end of the provision of Support that the data submitted to the Provider for publication via the information system for research, development and innovation are up to date and to correct them if they have changed.
3. The rights and obligations in transferring and providing data to the R&D&I IS are governed by the provisions of the TD and the relevant generally binding legal regulations.

XV. Withdrawal from the Contract

1. If the Beneficiary or any other entity involved in the Project violates any of its obligations under this Contract or the Contract or generally binding legal regulations, the Provider is always entitled to withdraw from this Contract.

2. Furthermore, the Provider is always entitled to withdraw from this Contract if any of the following occurs:
    a. if this Contract does not become effective for any reason no later than 60 days after its execution;
    b. if the Beneficiary loses its eligibility to implement the Project resulting from generally binding legal regulations and the TD, in particular if the Beneficiary ceases to be authorized to implement the Project as required by a specific legal regulation or if the Beneficiary enters liquidation or a petition for the opening of insolvency proceedings is filed against the Beneficiary;
    c. if the Beneficiary – a legal entity is dissolved without liquidation (e.g. in case of conversion of a legal entity according to the relevant legislation) or if the rights or obligations of the Beneficiary under this Contract should be assumed by any other entity on the basis of any legal fact;
    d. if, at any time after the execution of this Contract, it becomes known that the Beneficiary, the Investigator, other Participant or Co-investigator has in any way participated or is participating or is to participate in any Project with the same or similar issues as the Project, and such Project has received, is receiving or will receive Support from another source, or it becomes known that the Beneficiary, the Investigator, other Participant or Co-investigator must have been aware of the existence of such Project prior to the submission of the Project Proposal without having participated in such Project itself;
    e. if, at any time after the execution of this Contract, it becomes apparent that the Beneficiary has provided false, incomplete or misrepresented information in the Project Proposal or has submitted a Project Proposal prepared in violation of the Bidding Documents;
    f. if, at any time after the conclusion of this Contract, it becomes apparent that the Project Proposal did not have the proper requirements in accordance with the relevant provisions of the Contract;
    g. if at any time after the conclusion of this Contract it becomes apparent that the Beneficiary has failed to comply with any of its information obligations under this Contract, the Contract or generally binding legal regulations in a proper or timely manner;
    h. if at any time after the execution of this Contract it becomes apparent that the Beneficiary has not met the eligibility requirements for the Project;
    i. if, at any time after the execution of this Contract, any of the statements or confirmations of the Beneficiary (Applicant) or the Investigator (Proposer) in the Project Proposal are found to be false;
    j. if, at any time after the execution of this Contract, any of the statements, representations or warranties of the Beneficiary contained in this Contract are found to be false;
    k. if a Project outcome is claimed as a result that is not related to the Project topic at all.
3. Furthermore, the Provider shall be entitled to withdraw from this Contract in cases where such entitlement of the Provider is specified in individual provisions of this Contract or the TD or where it results from generally binding legal regulations.
4. Withdrawal from this Contract must be in writing and delivered to the other party. This Contract shall terminate upon withdrawal from this Contract when the written expression of the Party's intention to withdraw from this Contract is delivered to the other Party.
5. If the Provider withdraws from this Contract for any reason, any other obligations of the Beneficiary provided for this case by generally binding legal regulations, this Contract or the TD are not affected. In particular, the withdrawal from this Contract shall be expressly without prejudice to any penalties, claims for Contractual fines, default interest or claims for damages arising out of or under this Contract.
6. In the event of the liquidation of the Beneficiary, the Beneficiary is obliged to return to the Provider the unused funds from the Special-purpose Support and to hand over to the Provider an inventory of all tangible and intangible assets that have an independent economic purpose and whose entry price is higher than CZK 40,000 (or CZK 80,000 according to the amendment to Act No.586/1992 Coll, on income taxes, valid as of 1.1.2021), or CZK 60 000,- and an operational and technical function longer than one year, acquired from special-purpose Support. The Provider will decide on the further use of this property. The Beneficiary's right to dispose of the above-mentioned property is limited by the prior written consent of the Provider.

XVI. Penalties for Breach of Contract

1. The Provider shall be entitled to apply sanctions against the Beneficiary in the event of a breach of the obligations under this Contract by the Beneficiary or another Participant.

2. If the Beneficiary/other Participant breaches any of the following obligations:

   a. the obligation to use the Special-purpose Support exclusively for the stated purpose as set forth in Article VIII, paragraph 1, second sentence of this Contract,

   b. the obligation to provide only true, complete and undistorted information in the partial reports, final reports or any other documents (notifications, requests, information, etc.) delivered to the Provider as set out in Article X. paragraph 4, first sentence of this Contract,

   c. any of its obligations set out in the Contract and in this Contract,

   d. the obligation to deliver to the Provider, in due and timely manner, true and complete information on the use of the allocated Special-purpose Support for the Project dealt with by the Beneficiary in the previous calendar year in the prescribed manner and within the time limit specified in Article IX, paragraph 4 of this Contract,

   e. to duly and timely submit to the Provider a partial report with the specified particulars and in the specified manner,

   f. to submit a final report to the Provider in due and timely manner and with the specified particulars,

   g. to process the data for the Research, Experimental Development and Innovation Information System in a proper and timely manner and to deliver the data to the Provider,

   it constitutes a breach of the conditions under which the funds were granted and therefore an unjustified use of State budget funds within the meaning of Section 3(e) of the Financial Regulation. In such a case, it constitutes a breach of budgetary discipline under Section 44 of the Budgetary Rules and the Beneficiary is obliged to proceed in accordance with Section 44a of the Budgetary Rules. Furthermore, the Provider shall be entitled to impose a Contractual penalty of up to 1% of the amount specified in Article II, paragraph 2 of this Contract for each individual case of breach of the obligation referred to in points a) – d) of paragraph 2 of this Article. And for breach of the obligation referred to in points e) – g) of paragraph 2 of this Article of the Contract, a Contractual penalty of CZK 500,- (five hundred Czech crowns) for each calendar day of delay in fulfilling the obligation. The Beneficiary is obliged to pay the Contractual penalty within 15 days from the date of receipt of the letter of reproach and the notice to pay the Contractual penalty.

3. In the event that during the control of the implementation of this Contract (in the form of a partial or final Project report, control of the Beneficiary/other Participant, public financial control, etc.), the Provider finds that the information communicated by the Beneficiary and expressing the conditions to which the Provider attaches the granting of the special-purpose Support is incomplete or untrue, the Provider is entitled to initiate proceedings for withdrawal of the Special-purpose Support and to impose the repayment of the Special-purpose Support or part thereof already granted to the Beneficiary (see Section 15(1) and (3) of the Budget Rules).

4. In case the Provider finds that the Beneficiary/other Participant has violated other provisions of this Contract (other conditions of the Grant) or the TD, the Provider may withdraw from this Contract, decide to stop providing the special-purpose Support or impose on the Beneficiary (and on behalf of the other Participant) the repayment of the unjustified special-purpose Support. A breach under the preceding sentence of this paragraph shall mean, in particular, failure to meet the schedule or deliverables or any of the objectives set out in the Project Proposal, or any other reason on the part of the Beneficiary that affects the performance of this Contract (i.e. death of the Investigator, termination of his/her employment relationship with the Beneficiary).

5. If the Beneficiary fails to fulfil any of its monetary obligations under this Contract or the TD (in particular the obligation to reimburse unspent funds) to the Provider properly or on time, the Beneficiary is obliged to pay the Provider a Contractual penalty of 0.01% of the amount due for each day of delay in fulfilling the obligation, as well as default interest at the statutory rate.

6. If the Beneficiary breaches any of its obligations under this Contract, the Provider shall be entitled to suspend the provision of Support under this Contract without further delay until the Beneficiary remedies the defective condition and takes such measures as will ensure that the Provider does not commit any further breaches.

7. In the case of a final evaluation of a completed Project in category "S" according to Article XIII, paragraph 5, the Provider is entitled to request the Beneficiary to reimburse the subsidy according to the degree of non-fulfillment of the assignment, up to 100% of the Special-purpose Support drawn for the entire duration of the Project. The amount of the repayment of the special-purpose Support will be assessed individually on the proposal of the expert bodies of the AZV. In the event that the obligation to repay the special-purpose Support is imposed, the Beneficiary shall be obliged to return the Special-purpose Support (or part thereof) to the State budget upon the Provider's written request, no later than within 30 days from the date of receipt of the request.

XVII. Rights to the Results of the Project

1. All rights to the results of the Project belong to the Beneficiary. The rights of the authors and originators of the results and the owners of the protective rights to them are regulated by specific generally binding legal regulations.
2. For the use of the results, the following applies
    a. if the Beneficiary is a Research Organization or research infrastructure operator and has exclusive rights to a result fully funded by public funds, the exploitation of the results is possible in particular through teaching, public dissemination of research results on a non-exclusive and non-discriminatory basis or knowledge transfer
    b. if the Beneficiary of the Special-purpose Project Support is an Enterprise together with a Research Organization or research infrastructure operator, then the results of (1) this cooperation, which cannot be protected under the laws governing the protection of the results of copyright, inventive or similar creative activity, may be freely disseminated and the rights to the results resulting from the activities of the Research Organization or research infrastructure belong fully to these Beneficiaries, or (2) any rights to the results of the Project, as well as related access rights, shall accrue to all collaborating entities to the extent appropriate to the extent of their participation in the Project; or (3) the Research Organization or research infrastructure operator shall receive compensation from the collaborating Enterprise equivalent to market prices for rights in the Project results arising from their activities which are assigned to the collaborating Enterprise or to which the latter has acquired access rights.
3. The Beneficiary is obliged to ensure the management of research data collected or generated during the Project and to provide information on the availability and dissemination of research results and research data in accordance with the principle that research results and research data are not made public only in justified cases
4. The Beneficiary is obliged to submit to the Provider, no later than the final report on the Project, a plan for putting the achieved results into practice (the so-called implementation plan). The details of the implementation plan shall be published by the Provider on its website together with the instructions to the final Project report.
5. The Beneficiary is obliged to make the results of the Project available to all interested parties on equal terms, by publishing them in the trade press and by giving lectures within six months of the end of the Project. In the event of non-compliance with this condition, the Project may be awarded a final rating of 'S' with all the ensuing consequences.

XVIII. Dispute Resolution, General and Final Provisions

1. Any disputes between the parties to this Contract arising under or in connection with this Contract shall be settled, in the absence of agreement between the parties, by the competent court of the Czech Republic, unless otherwise provided by law.
2. Terms used in the text of this Contract shall have the same meaning as similar terms used and defined in the WD, except for terms expressly defined in the text of this Contract.
3. This Contract, all rights and obligations of the parties under this Contract, as well as all relations between the parties to this Contract based on or related to this Contract shall be governed by the legal order of the Czech Republic and, within its framework, in particular by the Act, Act No. 89/2012 Coll., the Civil Code and Act No. 218/2000 Coll., on budgetary rules and on amendments to certain related acts (budgetary rules), as amended.
4. Any changes that are material to the fulfilment of the conditions under which the Beneficiary has been granted Support under this Contract must be notified in writing by the Beneficiary to the Provider within 7 days of becoming aware of their occurrence.
5. The Beneficiary shall not be entitled to set off against any claims of the Provider arising out of or under this Contract any of its claims against the Provider. The Beneficiary shall not assign any claim against the Provider arising under or in connection with this Contract without the prior written consent of the Provider.
6. Neither withdrawal from this Contract nor the parties' agreement to terminate this Contract (unless otherwise specified) shall affect any right to claim penalties under this Contract or damages under this Contract.
7. The Beneficiary undertakes to ensure that the Investigators are remunerated in accordance with Act No. 262/2006 Coll., the Labor Code, as amended, and Government Regulation No. 341/2017 Coll., on salary ratios of employees in public services and administration, as amended. The use of other personal expenses (OPE) in contributory organizations and other payments for work performed in the organizational units of the State is carried out in accordance with the applicable regulations, in particular in accordance with the Labor Code.
8. The use of special-purpose Support for business trips on the part of the Beneficiary and another Participant,

which may be related only to the Project solution, or to the active presentation of the results of the Project solution, research or scientific activities carried out within the approved Project, is subject to the approval of the Provider. Work trips of the Beneficiary/other Participant may be allowed on the basis of the opinion (recommendation) of the Project Investigator. Work trips undertaken for the purpose of participating in professional conferences and seminars (domestic and foreign) must be specified in the Project Proposal or, at the latest, in the Sub-Project Report or Final Project Report and must be approved by the Provider.

9. The Project, the method of its solution and its expected results are not classified information within the meaning of Act No. 412/2005 Coll., on the protection of classified information and security competence, as amended.

10. The following Annexes form an integral part of this Contract:

    a. Approved Project proposal (including any reduction in the total amount of Special-purpose Support required) – available in the Application at http://eregpublic.ksrzis.cz/

    b. Terms and conditions of the Project – TD Annex 8 – available on the website of the Provider or the AZV

    c. Annex. 1 – Breakdown of Recognized Costs and Special-purpose Support for each year of the Project

11. The invalidity of any provision of this Contract shall not affect the validity of this Contract as a whole or the validity of any other part of this Contract.

12. If this Contract is to be executed in paper form, it shall be executed in two (2) counterparts, one (1) copy to be given to each party.

XIX. Validity, Effectiveness, Form, Duration and Amendments to the Contract

1. This Contract shall come into force on the date of its signing by the last party.

2. The effectiveness of this Contract is subject to a condition precedent, which is that the Beneficiary has duly demonstrated to the Provider its eligibility for the Project within the meaning of the relevant generally binding legal regulations and the TD. This Contract shall become effective upon fulfilment of this condition precedent.

3. The Beneficiary declares that he/she is aware of the fact that the Provider is an obliged person within the meaning of Act No. 106/1999 Coll., on free access to information, as amended, and is thus obliged to make available all information about this Contract and the legal relationship based on it that is not excluded from disclosure by law, and expressly acknowledges that this Contract will be published by the Provider in the Register of Contracts pursuant to Act No. 340/2015 Coll, on Special Conditions of Effectiveness of Certain Contracts, Publication of Such Contracts and on the Register of Contracts (hereinafter referred to as the Register of Contracts Act), as amended.

4. This Contract shall enter into force on the date of its publication in the Register of Contracts pursuant to the Act on the Register of Contracts, subject to the condition precedent under paragraph 2 of this Article.

5. This Contract is concluded between the Parties for a definite period of time, namely for the duration of the Project, including the period of 180 days from the date of completion of the Project referred to in Article I, paragraph 4 of this Contract, necessary for the evaluation of the Project pursuant to Article XIII. The Contract and a maximum period of 10 years for the evaluation of the results of the Project, including the financial settlement of the Support provided in accordance with the budgetary rules. The validity and effectiveness of the Contract may be extended.

6. Any changes or additions to this Contract may be made only under the terms and in the manner specified in the Specification for Changes to the Project Solution, and in principle, unless otherwise provided for in the Contract Documents or a generally binding legal regulation, in writing by means of numbered addenda. No other form of amendment to this Contract shall be permitted.

7. The parties declare that this Contract has been made according to their true and free will, that they have read the Contract, that they agree with its contents and that they have affixed their handwritten signatures to prove it.

For the Provider	For the Beneficiary[1)]
In Prague on	In .....on.....
.....	.....
prof. MUDr. Vlastimil Válek, CSc., MBA, EBIR Minister	

Czech Republic – Ministry of Health

[1)] In the case of the Beneficiary – a legal entity or an organizational unit of the State or a local self-government unit, please also indicate the name, surname and function of the person(s) acting.

Annex 1 – Breakdown of Recognized Costs and Special-purpose Support for Each Year of the Project

1st year

For the **first year of the** Project, the Recognized Costs and Special-purpose Support to be provided by the Provider to the Beneficiary:

Beneficiary:	xxxxxxxx	ID:	Xxxxxx
Investigator:	xxxxxxx	born:	Xxxxxx
Other operating costs:		xxxx CZK	
Cost of fixed assets:		xxxx CZK	
Personal costs:		xxxx CZK	
Total costs:		xxxx CZK	
Of which the Provider's subsidy is:		xxxx CZK	

Of this amount, the Beneficiary shall transfer to other Participants, unless they are a governmental unit, the portion of the Designated Funds set forth below. The Provider shall transfer the funds to the other Participants – organizational units of the State – by means of a budgetary measure and the amount transferred to the Beneficiary shall be reduced by this part.

Co-beneficiary:	xxxxxxxx	ID:	Xxxxxx
Co-investigator:	xxxxxxx	born:	Xxxxxx
Other operating costs:		xxxx CZK	
Cost of fixed assets:		xxxx CZK	
Personal costs:		xxxx CZK	
Total costs:		xxxx CZK	
Of which the Provider's subsidy is:		xxxx CZK	

2nd year

For the **second year of the** Project, the Recognized Costs and Special-purpose Support to be provided by the Provider to the Beneficiary:

Beneficiary:	xxxxxxxx	ID:	Xxxxxx
Investigator:	xxxxxxx	born:	Xxxxxx
Other operating costs:		xxxx CZK	
Cost of fixed assets:		xxxx CZK	
Personal costs:		xxxx CZK	
Total costs:		xxxx CZK	
Of which the Provider's subsidy is:		xxxx CZK	

Of this amount, the Beneficiary shall transfer to other Participants, unless they are a governmental unit, the portion of the Designated Funds set forth below. The Provider shall transfer the funds to the other Participants – organizational units of the State – by means of a budgetary measure and the amount transferred to the Beneficiary shall be reduced by this part.

Co-beneficiary:	xxxxxxxx	ID:	Xxxxxx
Co-investigator:	xxxxxxx	born:	Xxxxxx
Other operating costs:		xxxx CZK	
Cost of fixed assets:		xxxx CZK	
Personal costs:		xxxx CZK	
Total costs:		xxxx CZK	
Of which the Provider's subsidy is:		xxxx CZK	

3rd year

For the **third year of the** Project, the Recognized Costs and Special-purpose Support to be provided by the Provider to the Beneficiary:

Beneficiary:	xxxxxxxx	ID:	Xxxxxx
Investigator:	xxxxxxx	born:	Xxxxxx
Other operating costs:		xxxx CZK	
Cost of fixed assets:		xxxx CZK	
Personal costs:		xxxx CZK	
Total costs:		xxxx CZK	
Of which the Provider's subsidy is:		xxxx CZK	

Of this amount, the Beneficiary shall transfer to other Participants, unless they are a governmental unit, the portion of the Designated Funds set forth below. The Provider shall transfer the funds to the other Participants – organizational units of the State – by means of a budgetary measure and the amount transferred to the Beneficiary shall be reduced by this part.

Co-beneficiary:	xxxxxxxx	ID:	Xxxxxx
Co-investigator:	xxxxxxx	born:	Xxxxxx
Other operating costs:		xxxx CZK	
Cost of fixed assets:		xxxx CZK	
Personal costs:		xxxx CZK	
Total costs:		xxxx CZK	
Of which the Provider's subsidy is:		xxxx CZK	

4th year

For the **fourth year of the** Project, the Recognized Costs and Special-purpose Support to be provided by the Provider to the Beneficiary:

Beneficiary:	xxxxxxxx	ID:	Xxxxxx
Investigator:	xxxxxxx	born:	Xxxxxx
Other operating costs:		xxxx CZK	
Cost of fixed assets:		xxxx CZK	
Personal costs:		xxxx CZK	
Total costs:		xxxx CZK	

Of which the Provider's subsidy is:	xxxx CZK

Of this amount, the Beneficiary shall transfer to other Participants, unless they are a governmental unit, the portion of the Designated Funds set forth below. The Provider shall transfer the funds to the other Participants – organizational units of the State – by means of a budgetary measure and the amount transferred to the Beneficiary shall be reduced by this part.

Co-beneficiary:	xxxxxxxx	ID:	Xxxxxx
Co-investigator:	xxxxxxx	born:	Xxxxxx
Other operating costs:		xxxx CZK	
Cost of fixed assets:		xxxx CZK	
Personal costs:		xxxx CZK	
Total costs:		xxxx CZK	
Of which the Provider's subsidy is:		xxxx CZK	

End of Annex 1

Annex 2 – Model Affidavit of Eligibility

Affidavit of the Applicant or Natural Person Co-Applicant Proving Their Eligibility

Applicant or **Co-Applicant**:

Name of the Applicant or Co-applicant [1)] : .....

Residence of the Applicant or Co-applicant [1)] : .....

Date of birth of the Applicant or Co-applicant [1)] : .....

Place of business of the Applicant or Co-applicant [1), 2)] : .....

Applicant's or Co-Applicant's registration number [1), 2)] : .....

(hereinafter referred to as the "**Applicant**" or "**Co-applicant**")

hereby, pursuant to the provisions of Section 18 (2) of Act 130/2002 Coll., on the Support of Research, Experimental Development and Innovation from Public Funds and on Amendments to Certain Related Acts (the Act on Support of Research, Experimental Development and Innovation), as amended

solemnly declares that:

- is not in liquidation and its bankruptcy or threatened bankruptcy is not resolved in insolvency proceedings,

- has settled its due obligations in relation to the State budget or the budget of the local self-government unit and other due obligations towards the State, State fund, health insurance company or the Czech Social Security Administration,

- has not been finally convicted of a criminal offence the substance of which is related to the Applicant's Enterprise, or of an economic offence or an offence against property, or is deemed to be so convicted by law,

- has not been disciplined in the last three years according to special legal regulations governing the performance of professional activities, if these activities are related to the subject of the public tender in research, experimental development and innovation,

- is not in an employment or other similar relationship with the legal entity entrusted with the organization of the public tender in research, experimental development and innovation pursuant to Section 23 (2) of the Act

- is a natural person who is not an Enterprise in difficulty under directly applicable European Union legislation

- a recovery order has not been issued against him following a decision of the European Commission in accordance with a directly applicable regulation of the European Union

I hereby solemnly declare that the information given in this document is true and correct. I am fully aware that, that if I provide false information, I will face all legal consequences.

In ..... of ..... [1)]

.....

signature of the Applicant or Co-applicant

[1)] Fill in the details on a computer, by machine or in block letters.
[2)] To be filled in if the Applicant or Co-applicant is an entrepreneur within the meaning of Act No. 455/1991 Coll., on Trade Enterprise (Trade Licensing Act), as amended.

Affidavit of the Applicant or Legal Entity Co-Applicant to Prove Eligibility

I. Applicant or Co-Applicant:

The business name or name of the Applicant or of the Co-Applicant [1)] : .....

Applicant's address or Co-applicant's address [1)] : .....

Applicant's or Co-applicant's registration number [1)] : .....

Registered in the Commercial Register maintained at[1), 2)] ....., section ....., insert .....

Represented by all persons who form the statutory body of the Applicant or Co-applicant or are members of the statutory body of the Applicant or Co-applicant (as listed in Section III of this declaration) (hereinafter referred to as the '**Applicant**' or '**Co-applicant**').

Type of entity of the Applicant or **Co-applicant** *in terms of CEP*.....

Type of entity of the Applicant or **Co-applicant** *in terms of CEDR*.....

II. Affidavit of the Applicant or **Co-applicant**

The Applicant or Co-applicant hereby, pursuant to Section 18 (2) of Act No. Act 130/2002 Coll., on the Support of Research, Experimental Development and Innovation from Public Funds and on Amendments to Certain Related Acts (the Act on Support of Research, Experimental Development and Innovation),

solemnly declares that:

- is not in liquidation and its bankruptcy or threatened bankruptcy is not resolved in insolvency proceedings,

- has settled its due obligations in relation to the State budget or the budget of the local self-government unit and other due obligations towards the State, State fund, health insurance company or the Czech Social Security Administration,

- has not been finally convicted of a criminal offence the substance of which is related to the subject of the business (activity), or of an economic offence, or of an offence against property, or is regarded as such by law

- has not been disciplined in the last three years according to special legal regulations governing the performance of professional activities, if these activities are related to the subject of the Public Tender in Research, Experimental Development and Innovation,

- is a legal person which is not an Enterprise in difficulty under directly applicable European Union law,

- a recovery order has not been issued against him following a decision of the European Commission under a directly applicable European Union regulation.

III. Persons forming the statutory body of the Applicant or **Co-applicant (or being a member of the statutory body of the Applicant** or **Co-applicant):**

Name and surname, function [1)] :	born. .[1),] :	Resident[1)] :
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....

(In the event of insufficient space, please provide the relevant details of the additional persons on a separate sheet clearly marked as an annex to the affidavit.)

IV. Affidavit of persons forming the statutory body of the Applicant or **Co-applicant or being a member of the statutory body of the Applicant** or **Co-applicant:**

The persons named above in Section III of this affidavit are hereby, pursuant to Section 18(2) of the Act

do solemnly declare that

- none of these persons has been disciplined in the last three years under the special legislation governing the exercise of professional activities, if these activities are related to the subject of the tender in research, development and innovation,
- none of these persons has been convicted of a criminal offence the substance of which is related to the business (activity) or an economic offence or an offence against property, or is regarded as such under the law,
- none of these persons is in an employment or other similar relationship with the legal person entrusted with the organization of the public tender in research, experimental development and innovation pursuant to Section 23(2) of the Act 130/2002 Coll.

The persons named above in Section III of this affidavit hereby declare on oath that the information given in this document is true and correct. They are fully aware that if they make false statements they will face all the legal consequences arising therefrom.

In ..... on .....[1)]

.....

signatures of **all** persons forming the statutory body of the Applicant or Co-applicant

or **all** members of the statutory body of the Applicant or Co-applicant

---

[1)] *Fill in the details on a computer, by machine or in block letters.*

[2)] *To be filled in if the Applicant or Co-applicant is registered in the Commercial Register.*

Annex 3 – Affidavit Pursuant to Budgetary Rules

Affidavit of the Applicant or Co-applicant as a Legal Entity on the Project Proposal of AZV as an Application for Subsidy Pursuant to Budgetary Rules

Subsequent details are to be completed by the Applicant/Co-applicant on a computer, by machine or in block capitals. If the information does not apply to the Applicant or Co-applicant, it shall be filled in 'not applicable'.

I. Applicant or Co-applicant:

the name or business name of the Applicant or Co-applicant:	
the address of the Applicant or Co-applicant:	
The registration number of the Applicant or Co-applicant:	
registered in the Commercial Register [1)]	
- held at	
- in the section	
- insert.	

(hereinafter referred to as the '**Applicant** or **Co-applicant**').

II. Affidavit of the Applicant or Co-applicant

The Applicant or Co-applicant hereby declares on oath that the information provided below (as set out in points III to VI of this declaration), as stipulated in Section 14(3)(e) of Act No 218/2000 Coll. on Budgetary Rules and on Amendments to Certain Related Acts (Budgetary Rules), as amended, is true and complete.

III. Identification of all persons acting on behalf of the Applicant or Co-applicant indicating whether they are acting as its statutory body or acting under a power of attorney (§ 14, paragraph 3, point e), point 1 of the Act 218/2000 Coll.)[2),3)] :

title, name, surname/name of the legal entity:	
date of birth/ID number:	
permanent residence/headquarters:	
Acting a) as its statutory body b) on the basis of a power of attorney	

IV. Identification of persons with a share in a legal entity that is an Applicant or Co-applicant (§ 14, paragraph 3, letter e), point 2 of Act No. 218/2000 Coll.) [3), 4)] :

title, name, surname/name of the legal entity:	
date of birth/ID number:	
permanent residence/headquarters:	

the amount of the shareholding in that legal entity which is the Beneficiary or other Participant:	

V. Identification of the persons in which the legal entity which is the Applicant or Co-applicant has a shareholding and the amount of such shareholding (Article 14, paragraph 3, point 3, letter e) of Act No. 218/2000 Coll.) [3), 5)] **:**

the name of the legal entity:	
Headquarters:	
ID:	
the amount of the shareholding in that legal entity:	

In ..... on .....

.....

signatures of **all** persons forming the statutory body of the Applicant or Co-applicant

or **all** members of the statutory body of the Applicant or Co-applicant

---

[1)] *To be filled in if the Applicant is registered in the Commercial Register.*

[2)] *To be completed by all Applicants/Co-applicants.*

[3)] *If necessary, copy points III to VI or, in the event of insufficient space, provide the relevant information in points III to VI on a separate sheet clearly marked as an annex to the affidavit.*

[4)] *To be filled in by all Applicants/Co-applicants except **those who are a State organizational unit, State-funded organization, public research institution, public or State university**.*

[5)] *To be filled in by all Applicants/Co-applicants except **those who are an organizational unit of the State and a State-funded organization**.*

[6)] *To be completed by all Applicants/Co-applicants.*

Annex 4 – Affidavit for Research Organizations

Affidavit of Eligibility of the Applicant or Co-applicant for Research Organizations

To be submitted by all Applicants and all Co-applicants.

I. Applicant or Co-applicant:

Title:
Headquarters:
ID:

hereby declares that it is, within the meaning of Section 33a of Act No. 130/2002 Coll.**, a Research Organization engaged in research and development and, according to the definition of the type of Research Organization set out below, meets all the conditions set out in the Framework for State Support for Research, Development and Innovation (2014/C 198/01).**

Research Organization

Article 1.3(e) of the Framework,

'Research and Knowledge Dissemination Organization' or 'Research Organization' means an entity (e.g. a university or research institute, a technology transfer agency, an innovation intermediary, a physical or virtual collaborative research entity), regardless of its legal status (established under public or private law) or method of funding, whose main objective is to carry out independently basic research, industrial research or experimental development or to disseminate publicly the results of these activities through teaching, publications or knowledge transfer. If the body also carries out economic activities, separate accounts must be kept for the funding, costs and income of these economic activities.

Enterprises that may exercise decisive influence over such an entity, e.g. as shareholders or members, may not have preferential access to the results it has achieved.

Article 2.1 of the Framework, Section 2.1.1 Public financing of non-economic activities

Where the same entity carries out activities of both an economic and a non-economic nature, public financing of non-economic activities will not fall within the scope of Article 107(1) of the Treaty if, in order to effectively avoid cross-subsidization of economic activities, the two types of activities, as well as the relevant costs, financing and revenues, can be clearly separated. Evidence of the proper allocation of costs, financing and revenues may be provided in the annual financial statements of the entity concerned.

19. The Commission considers that the following activities are generally of a non-economic nature:

a) primary activities of Research Organizations and research infrastructures, in particular:

- training to increase the numbers and improve the skills of human resources. In accordance with the Commission's case-law and decision-making practice, and in accordance with the Communication on the concept of State Support and the Communication on services of general economic interest, public education organized within the framework of the State education system, which is largely or wholly financed from State resources and controlled by the State, is considered to be a non-economic activity,

- Independent R&D to gain new knowledge and better understand the topic, including collaborative R&D where the collaboration in which the Research Organization or research infrastructure is involved is effective[1],
- public dissemination of research results on a non-exclusive and non-discriminatory basis, for example through teaching, open access databases, publicly available publications or open-source software;

(b) knowledge transfer activities, provided that they are carried out either by or on behalf of the Research Organization or research infrastructure (including its departments or branches) or jointly with or on behalf of other such entities and that any profits from such activities are reinvested in the primary activities of the Research Organization or research infrastructure. The non-economic nature of these activities shall be maintained even if the supply of the corresponding services is entrusted to third parties through an open procurement procedure.

20. Where a Research Organization or research infrastructure is used for both economic and non-economic activities, public funding is subject to State Support rules only if it covers the costs associated with the economic activities[2] . Where a Research Organization or research infrastructure is used almost exclusively for non-economic activities, its funding may fall entirely outside the scope of the State Support rules, provided that its economic use is purely incidental, i.e. it is an activity directly related to the operation of the Research Organization or research infrastructure and necessary for its operation or inextricably linked to its main non-economic use and limited in scope. According to the Commission, this condition will be met if the economic activities use exactly the same inputs (e.g. materials, equipment, labor and fixed capital) as the non-economic activities and the capacity allocated each year to these economic activities does not exceed 20 % of the total annual capacity of the entity.

In ..... on .....

.....

signatures of **all** persons forming the statutory body of the Applicant or Co-applicant

or **all** members of the statutory body of the Applicant or Co-applicant

---

[1] *The provision of R&D services and R&D carried out on behalf of Enterprises shall not be considered as independent R&D*

[2] *Where a Research Organization or research infrastructure is funded from both public and private sources, the Commission considers that this will be the case if the public funding allocated to the entity in a particular accounting period is greater than the costs incurred by the entity for non-economic activities in that period.*

Annex 5 – Sample Affidavit for Proving the Eligibility of an Applicant/Co-applicant Based Outside the Czech Republic

Affidavit Proving the Eligibility of the Applicant or Co-applicant – Natural Person Based Outside the Czech Republic

Applicant/Co-applicant:

Name and surname of the Applicant/Co-applicant, [1)] : .....

Residence of the Applicant/Co-applicant [1)] : .....

Date of birth of the Applicant/Co-applicant, [1)] : .....

Place of business of the Applicant/Co-applicant[1), 2)] : .....

Applicant's/Co-applicant's registration number,[1), 2)] : .....

(hereinafter referred to as "the **Applicant/Co-applicant**, ")

hereby, pursuant to the provisions of § 18 paragraph (2) of Act 130/2002 Coll., on the Support of Research, Experimental Development and Innovation from Public Funds and on Amendments to Certain Related Acts (the Act on Support of Research, Experimental Development and Innovation), as amended

solemnly declares that:

- has the appropriate authorization to operate, if required by special regulation

- is not in liquidation and its bankruptcy or threatened bankruptcy is not resolved in insolvency proceedings,

- has settled its due obligations in relation to the State budget or the budget of the local self-government unit and other due obligations towards the State, State fund, health insurance company or the Czech Social Security Administration,

- has not been convicted by a court of law of a criminal offence the substance of which is related to the business of the Applicant or Co-applicant or of an economic offence or an offence against property, or is deemed to be so convicted by law,

- has not been disciplined in the last three years under special legislation governing the performance of professional activities, if such activities are related to the subject of the public tender in research, experimental development and innovation,

- is a natural person who is not an Enterprise in difficulty under directly applicable European Union law,

- a recovery order has not been issued against him following a decision of the European Commission in accordance with a directly applicable regulation of the European Union

I hereby solemnly declare that the information given in this document is true and correct. I am fully aware that if I provide false information, I will face all legal consequences.

In ..... on .....[1]

.....

signature of the Applicant/Co-applicant

[1)] Fill in the details on a computer, by machine or in block letters.

[2)]To be filled in if the Applicant or Co-applicant is an entrepreneur within the meaning of Act No.455/1991 Coll., on Trade Enterprise (Trade Licensing Act), as amended.

Affidavit for Proving the Eligibility of an Applicant/Co-Applicant Based Outside the Czech Republic

I. Applicant/Co-applicant:

Business name or name of the Applicant/Co-applicant[1)] : .....

Applicant's/Co-applicant's address[1)] : .....

Applicant's/Co-applicant's registration number[1)] : .....

Registered in the Commercial Register maintained at[1), 2)] ....., section ....., insert .....

Represented by all persons who form the statutory body of the Applicant or Co-applicant or are members of the statutory body of the Applicant/Co-applicant (listed in section III of this declaration) (hereinafter referred to as '**Applicant**' or '**Co-applicant**').

Applicant/Co-applicant entity type *in terms of CEP*.....

Type of Applicant/Co-applicant entity *in terms of CEDR*.....

II. Affidavit of the Applicant or **Co-applicant**

Pursuant to Section 18 (2) of Act 130/2002 Coll., on the Support of Research, Experimental Development and Innovation from Public Funds and on Amendments to Certain Related Acts (the Act on Support of Research, Experimental Development and Innovation),

solemnly declares that:

- has the appropriate authorization to operate, if required by a specific regulation

- is not in liquidation and its bankruptcy or threatened bankruptcy is not resolved in insolvency proceedings,

- has settled its due obligations in relation to the State budget or the budget of the local self-government unit and other due obligations towards the State, State fund, health insurance company or the Czech Social Security Administration,

- is a legal person which is not an Enterprise in difficulty under directly applicable European Union law,

- a recovery order has not been issued against him following a decision of the European Commission under a directly applicable European Union regulation,

- has not been finally convicted of, or is deemed by law to have been convicted of, a criminal offence relating to the business (activity) of the Applicant or Co-applicant or of an economic offence or an offence against property.

III. Persons forming the statutory body of the Applicant/Co-applicant (or being a member of the statutory body of the Applicant/Co-applicant):

Name and surname, function[1)] :	Born[1)] :	Residence[1)] :
.....	.....	
.....	.....	
.....	.....	
.....	.....	

(In the event of insufficient space, please provide the relevant details of the additional persons on a separate sheet clearly marked as an annex to the affidavit.)

IV. Affidavit of the persons who form the statutory body of the Applicant/Co-applicant or are members of the statutory body of the Applicant or **Co-applicant:**

The persons named above in Section III of this affidavit are hereby, pursuant to Section 18(2) of the Act

do solemnly declare that

- none of these persons has been disciplined in the last three years under the special legislation governing the exercise of professional activities, if these activities are related to the subject of the Public Tender in Research, Development and Innovation,
- none of these persons has been finally convicted of an offence the facts of which are related to the subject matter of the business (activity) or for an economic crime or a crime against property, or are deemed to be so by law.

The persons named above in Section III of this affidavit hereby declare on oath that the information given in this document is true and correct. They are fully aware that if they make false statements they will face all the legal consequences arising therefrom.

In ..... on .....[1)]

.....

signatures of **all** persons forming the statutory body of the Applicant/Co-applicant

or **all** members of the statutory body of the Applicant/Co-applicant

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[1)] *Fill in the details on a computer, by machine or in block letters.*

[2)] *To be completed if the Applicant or Co-applicant is registered in the Commercial Register.*

Annex 6 – Opinions on the Project Proposal

(1) The following statements (P.6.1. and P.6.2.) are to be submitted as an annex to the Project proposal, where appropriate.

P6.1 Opinion of the ethics committee of the Applicant/other Participant

(1) The Applicant's ethics committee's opinion on the Project must be submitted whenever the Project involves the provision of health care, research with human subjects and also in the case of research with questionnaire survey methodology and qualitative investigations with persons affected by or at risk of disease in accordance with the International Ethics Committee for Biomedical Research with Human Participants CIOMS/WHO, 2002.

(2) The Ethics Committee shall here explicitly confirm the text of the attached "**Informed Consent of the Patient/Subject**" and shall be responsible for its accuracy in accordance with regulations if Informed Consent is required under the relevant law. In addition, it is necessary to in the case of foreseen work with human beings, a statement from the Ethics Committee on the protection of human beings.

(3) If the Applicant does not have an ethics committee, the ethics committee of the other Participant or the Ethics Committee for Multicenter Trials pursuant to the Medicinal Products Act No.

(4) An officially certified copy must be provided when concluding the Support Contract.

P6.2. Statement of the Expert Panel – Protection of Experimental Animals

(1) In the case of a proposed Project involving experimental work with animals, the Applicant shall provide a **valid approved "experimental Project",** specifically related to the Project in question, with the opinions of the expert committee of the user facility and the departmental committee of the relevant State authority pursuant to Act No. 246/1992 Coll. on the Protection of Animals against Cruelty, as amended, and Decree No. 419/2012 Coll. on the Protection of Experimental Animals, as amended. The experimental Project shall be documented by the Applicant with whom a Contract for the grant of Support is to be concluded or in whose favor a Decision on the increase in the budget is to be issued before the Contract is concluded or the Decision is issued. The experimental design enabling the relevant Project to be addressed shall be attached to each Project, but nothing prevents one experimental design from being attached to several Projects Supported by the Ministry of Health, provided that this is in accordance with the relevant legal provisions.

(2) An officially certified copy must be provided when concluding the Support Contract.

Annex 7 – Categorization of Evaluation Panels According to Their Expertise

(1) The Provider has established ten expert Evaluation Panels of the Czech Health Research Council (AZV) to which Applicants will submit their Project proposals (according to the professional focus of the Project):

P01 Metabolic and Endocrine Diseases
P02 Circulatory Diseases
P03 Cancer
P04 Nervous System and Mental Diseases
P05 Immune Disorders and Infectious Diseases
P06 Organ Dysfunction and Critical Care Medicine
P07 Age-specific Disease Groups
P08 Biomedical Technologies
P09 Preventive Medicine and Nursing
P10 Musculoskeletal Medicine

2) The focus of each Evaluation Panel is as follows:

P01 Metabolic and Endocrine Diseases

Panel 01 deals with metabolic aspects in the fields of: endocrinology and diabetology, clinical biochemistry and clinical pharmacology, medical genetics, pediatrics, gastroenterology, nephrology, rheumatology and other fields of internal medicine.

P02 Circulatory Diseases

Panel 02 deals with clinical and experimental research of cardiovascular diseases ranging from etiological and pathogenetic aspects to diagnostic, therapeutic and preventive issues of cardiovascular diseases. Priority is given to the potential of the acquired knowledge to be applied in clinical practice with the aim of improving existing diagnostic, therapeutic and preventive measures of cardiovascular medicine.

P03 Cancer

Panel 03 deals with experimental, clinical, preventive and epidemiological issues in cancer. In the field of research on carcinogenesis, molecular biology, genetics, pharmacology and immunology of cancer, the prefers innovative Projects with the potential for real application in oncological practice. Research in this covers a multidisciplinary spectrum of diagnostic, surgical, radiation, medical and other methods used or potentially applicable in oncology.

P04 Nervous System and Mental Diseases

Panel 04 deals with applied research in the field of etiopathogenesis, prevention, early diagnosis and treatment of psychiatric and neurological diseases in order to prevent, cure or minimize difficulties, improve functional capacity and quality of life of patients. These are mainly

neurodevelopmental diseases, mental disorders in adulthood, neurodegenerative, neurogenetic and neurometabolic diseases, vascular diseases of the brain, epilepsy, infectious and autoimmune diseases of the nervous system, neuro-traumatological, neurooncological and neurorehabilitation issues including clinical neurophysiology and neuropsychology. Topics include social aspects of neurological and psychiatric diseases and the organization of health service provision.

P05 Immune Disorders and Infectious Diseases

Panel 05 deals with the elucidation of the genetic basis, etiology, pathogenesis, diagnosis, treatment and prevention of human immunopathological diseases. These include inflammatory and autoimmune diseases, immunological hypersensitivity diseases and immunodeficiency diseases. Attention is also paid to immunological diagnostics and immunotherapy of other diseases. Communicable disease research focuses on the study of the causative agents, etiopathogenesis, diagnosis, prevention and therapy of major human infectious diseases threatening our population, including healthcare-associated infections.

P06 Organ Dysfunction and Critical Care Medicine

Panel 06 deals with the pathogenesis of diseases in the field of intensive, perioperative and transplantation medicine, especially their prevention and early detection, development of new therapies and methods and epidemiology. Organ-specific research includes mainly kidney diseases and urogenital tract, liver and gastrointestinal tract, respiratory system, ENT, eye and skin.

P07 Age-specific Disease Groups

Panel 07 deals with diseases that are specific to childhood or old age and meet at least one of the following criteria: 1. their typical course at this age is significantly different in the sense that they represent a general health problem, 2. the medical approach to these diseases in childhood or old age plays a leading role in the field, 3. they have a significantly higher incidence of in these age groups. Studying the impact of genetic factors and the external environment on the etiopathogenesis and pathophysiology of major childhood diseases and the elderly. The development of non-invasive diagnostic methods for diseases of childhood and elderly diseases and/or the development of preventive procedures and therapeutic methods to improve the quality of life of sick children and the elderly. The also includes certain diseases of pregnancy and the perinatal period if they may result in harm to the fetus and newborn.

P08 Biomedical Technologies

Panel 08 deals with biomedical and pharmaceutical technologies in the form of the development of new diagnostic and therapeutic methods in medical applications. It is biomedical technologies in the form of the development of new materials and technologies for the replacement of damaged human tissues, including the introduction of new surgical techniques using these materials and new therapeutic methods in medical applications. The Project should include experimental development or preclinical in vivo testing or implantation/use of these materials/processes/techniques in appropriate animal models and their introduction into clinical

practice. In addition, technologies aimed at the use or development of new devices (hardware and software) or molecular and pharmacological diagnostics.

P09 Preventive Medicine and Nursing

Panel 09 deals with preventive medicine, hygiene, epidemiology, public health and nursing. In the field of preventive medicine, the deals with preventive health care leading to improved health and quality of life at the individual and population level, specific and non-specific primary prevention including health risk assessment, and in the field of hygiene, protection and promotion of health and protection of healthy living conditions. In the field of epidemiology, the study of the prevalence of diseases and health disorders in the human population and the monitoring of factors that undermine or influence this prevalence, in particular environmental, lifestyle, health predispositions, climatic and social factors. Emphasis is placed on the prevention of the occurrence and spread of infectious diseases, including the characterization of the conditions of transmission and spread of micro-organisms, as well as of mass-occurring non-infectious diseases. In the field of public health, emphasis is placed on determinants of health, health policy objectives, strategies and instruments, macro and microeconomic approaches, management systems and their application in the management of health system and health facility organization, health care quality management, statistical and informatics Projects. In the field of nursing, the emphasis is on Projects focused on active processes of meeting the biological, psychological and social needs of the sick and healthy person in health care.

P10 Musculoskeletal Medicine

Panel 10 covers adult and pediatric trauma, congenital disorders and acquired disease in children and adults, musculoskeletal tumors, osteoporosis, anatomy and biomechanics of the musculoskeletal system, imaging. The need for "musculoskeletal medicine" is increasing with the aging of the population, the increase in injuries and degenerative diseases. These include osteoporotic fractures (proximal femur, distal radius, spine, proximal humerus), osteoarthritis, rheumatologic musculoskeletal disorders, joint replacement (hip, knee, shoulder), spinal disorders and injuries, trauma including sports, intra-articular development, developmental disorders (hip dysplasia), osteoporosis, tumors including metastasis and pathological fractures and other topics.

Annex 8 – Project Terms and Conditions

P8.1 Procedure for concluding a Contract for the provision of Special-purpose Support or for issuing a Decision on a budget increase

(1) The time limit and the method of concluding a Contract on the provision of Special-purpose Support or issuing a Decision on the budget increase are laid down in Section 25 of the Act The Provider shall notify each Applicant in writing of the Decision on the acceptance of the Project proposal for the Project and send the Beneficiary a draft Contract or, for a Beneficiary organizational unit of the State or an organizational unit of the Ministry, issue a Decision on the budget increase and implement a budget measure in accordance with the budget rules; the Contract or Decision shall set out the binding conditions for the provision of Special-purpose Support and shall set out the obligations of both the Beneficiary and the Investigator.

(2) Failure to comply with the time limit set by the Provider for the conclusion of a Contract for the provision of special-purpose Support or for the issuance of a Decision to increase the budget, due to reasons on the part of the Beneficiary, shall entitle the Provider, within the meaning of Section 25(2) of the Act, to conclude a Contract for the provision of special-purpose Support with the next Applicant in the order resulting from the results of the public tender or to issue a Decision to increase the budget in favor of such Applicant.

(3) The Beneficiary is entitled to accept or reject the delivered draft Contract as a whole and to return it without undue delay. The Beneficiary shall not be entitled to make any amendments or additions to the Support Contract, except for the addition of the Beneficiary's identification data required in the Contract; the Applicant shall instead be obliged to add such identification data to the Contract in the manner and places provided for in the Contract.

(4) The effectiveness of this Contract is subject to a condition precedent, which is that the Recipient has duly demonstrated to the Provider their eligibility for the Project within the meaning of the relevant generally binding legal regulations and the TD. If this condition precedent is fulfilled, the Contract shall become effective on the date of its publication in the Register of Contracts in accordance with Act No. 340/2015 Coll., on Special Conditions of Effectiveness of Certain Contracts, Publication of Such Contracts and on the Register of Contracts (Act on the Register of Contracts), as amended.

(5) The Decision shall be enforceable from the moment it is delivered to the Beneficiary. It is a condition of enforceability that the Beneficiary has demonstrated its eligibility for the Project according to the TD. If the Beneficiary and the other Participant are organizational units of the State under the competence of one budget chapter administrator, they do not provide each other with monetary benefits and the Provider shall define their mutual relations in the Decision on the budget increase.

(6) If one or more other Participants will be involved in the Project, the Beneficiary shall, within 30 calendar days at the latest of the entry into force of the Grant Contract, conclude with each such additional Participant a Contract for the implementation of a part of the Project in accordance with the terms and conditions set out in the Grant Contract and deliver such Contract together with all annexes to the Provider within that period; such Contract shall be concluded for the entire period during which the additional Participant is involved in the implementation.

P8.2. Conditions, timing and methods of granting Special-purpose Support

(1) Unless the budget spending is regulated as a result of a budgetary provisional period pursuant to the Act on Budgetary Rules, the Provider shall start providing Special-purpose Support for newly initiated Projects within 60 calendar days from the date of entry into force of the Contract or from the date of the Decision on the budget increase. If an additional Participant is involved in the Project, the Special-purpose Support can only start in the first year of the Project once their mutual agreement has been concluded and submitted to the Provider in accordance with Article 1.1(5) of this Annex.

(2) In the second and subsequent year of the Project, if the budget spending is not regulated as a result of the budget proviso according to the Budget Rules Act, the provision of the Special-purpose Support will start within 60 calendar days after the approval of the relevant partial Project report by the Provider, provided that the conditions set out in the Contract or Decision are met. For ongoing Projects, other conditions must be met:

a) according to § 10 of the Act, the condition for inclusion of data must be fulfilled to the information system of research, experimental development and innovation;
b) where an amendment to the Contract or Decision granting the Special-purpose allowance is to be concluded or issued for the year in question, it must take effect or be enforceable within that period.

(3) Pursuant to Section 10 of the Act, the Provider shall only provide special-purpose Support to the Beneficiary by direct transfer to the Beneficiary's bank account specified in the Contract. If another Participant, who is not an organizational unit of the State or an organizational unit of the Ministry, is involved in the Project, the Provider shall provide the Beneficiary with the special-purpose Support including the part of the special-purpose Support Special-purpose for the other Participant and the Beneficiary shall transfer to the other Participant the part of the special-purpose Support Special-purpose for him/her on the basis of their mutual agreement pursuant to Article 1.1(5) of this Annex, which the Beneficiary shall conclude with the other Participant on the basis of a Contract with the Provider.

(4) If another Participant is involved in the Project and its contribution to the Project is clearly specified in the Project proposal, the provision of part of the Special-purpose Support to the other Participant is not subject to the Public Procurement Act.

(5) If the Beneficiary or other Participant is an organizational unit of the State or an organizational unit of the Ministry, the Provider shall request the Ministry of Finance to implement a budgetary measure; the funds intended for this Beneficiary or other Participant shall be provided through the budget chapter of the respective founder.

P8.3. Conditions for the use of Special-purpose Support

(1) The Special-purpose Support shall be managed by the Beneficiary and the other Participant in accordance with the Contract or the Decision or any amendments thereto. Specific Support granted in accordance with the Contract, or Decision for the relevant calendar year shall be accounted for in that calendar year. Any adjustment to the use of the Grant for a given year may be made only in accordance with Article 5 of this Annex. Actions contrary to Article 5 of this

Annex shall constitute a breach of budgetary discipline and shall be grounds for withdrawal from the Contract or for a Decision to terminate the Support and other sanctions under the Financial Regulation Act.

(2) The use of Special-purpose Support must comply with the basic composition of the funds set out in in the Contract or Decision. If the approved Project budget differs in its composition or amount from the amounts requested in the Project proposal (or specified in the relevant sub-report), the Provider shall send an approved revised breakdown together with the Contract (or an amendment to the Contract or a new Decision), which is then binding on the Beneficiary and the other Participant. Unless otherwise specified in the TD, the Support disbursement and its composition shall be binding to two decimal places (CZK 0,01), regardless of the accuracy of the data provided, in accordance with Decree No 367/2015 Coll., on the principles and deadlines for financial settlement of relations with the State budget, State financial assets and the National Fund (Decree on financial settlement), as amended in the partial or final report.

(3) The Beneficiary is obliged to continuously control both the use of the special-purpose Support and the progress of the Project. It shall be responsible for ensuring that the special-purpose Support is used in accordance with the dispositions of the Investigator; however, if it finds that these guidelines are in breach of the regulations on the management of State property or that the funds are being used in an inefficient, ineffective or wasteful manner, it shall suspend the implementation of the disposition and inform the Provider.

(4) In accordance with the provisions of Section 8 (1) of the Act, the Beneficiary and other Participants shall keep separate accounting records of the management of the allocated Special-purpose Support in accordance with the composition of the eligible costs in order to be able to provide the Investigator with reliable data on the status of the disbursement for the purposes of the Provider and during the year without undue delay upon request. The method of recording provided for in Act No 563/1991 Coll., on accounting, as amended, shall be determined by the Beneficiary.

(5) All accounting documents used by the Beneficiary and the other Participant to prove the use of the Special-purpose Support must comply with the requirements of the Accounting Act and be marked with the number of the separate Special-purpose Support register of the respective Project. The separate accounting records must always show the registration number of the Project, all income and expenditure in this analytical account for the year, the date and reason/purpose of each item (it must be clearly linked to the Project), the amount in CZK and the classification of the item according to the Beneficiary's accounting schedule. If funds other than the Special-purpose Support provided (Support from other public sources, Support from non-public sources, own resources, etc.) are used for the Project, the Project statement must indicate how these other funds were used. The Beneficiary is also obliged to submit accounting documents proving the use of these other funds when auditing (both interim and ex-post) the management of the special-purpose Support during the Project.

(6) The Beneficiary shall submit to the Provider annually in the partial or final reports a detailed overview of the use of the recognized costs and the Special-purpose Support provided for the entire Project, including the amount of unspent Special-purpose Support and funds transferred to the Special-purpose Support fund established in accordance with Act No. 111/1998 Coll,

341/2005 Coll., on Public Research Institutions, as amended, up to 5 % of the amount of Special-purpose Support granted for the Project, except for the last year of the Project, when all funds allocated to the Project must be accounted for. Data on the use of funds by the Beneficiary and the other Participant shall be provided. Unspent Special-purpose Support from a given calendar year (unless transferred to the Special-purpose fund by the eligible entities) may be used by the Beneficiary or other Participant in subsequent years of the Project in accordance with the approved Project Proposal, i.e. for the same purpose for which they were approved by the Provider. Any changes during the year must be justified in the periodic sub-reports.

(7) By 15 February of each subsequent year, each Beneficiary is obliged to send to the Provider an accounting of the subsidies provided to the Beneficiary in the previous year (the Beneficiary shall indicate the amount allocated to each of the Provider's Projects and the amounts spent on non-investment costs and on the costs of acquiring tangible and intangible fixed assets for the entire accounting period of the previous year and information on the transfer to the Special-purpose fund, if the Beneficiary is able to create an Special-purpose fund) in accordance with the layout provided on the Provider's website, to the electronic address veda@mzcr.cz. This information is processed by the Provider in accordance with specific legal provisions and forwarded to the Ministry of Finance in the course of the financial settlement with the State budget.

(8) The Beneficiary manages the Special-purpose Support provided. If the Beneficiary transfers part of the Special-purpose Support to another Participant, in accordance with the terms of the Contract or Decision of the Special-purpose Support and on the basis of a specific agreement on the Project part concluded between them, the part of the Special-purpose Support so granted shall be further managed by the next Participant who shall be obliged to comply with all obligations under that Contract. The Beneficiary shall in this case, the obligation to also control the management of the special-purpose Support transferred to the other Participant.

(9) If, during the course of a given Project year, the Beneficiary or other Participant discovers, that facts have arisen requiring changes or transfers from the composition of the eligible costs or the Special-purpose Support provided as specified in the Contract or Decision and its annexes, he/she shall proceed as set out in Article 5 of this Annex.

(10) If the Beneficiary or another Participant is entitled to create a special-purpose fund on the basis of special legal regulations and makes use of this right for a given Project, it is obliged to draw down and account for the fund created in the course of the Project no later than the last day of the last calendar year of the Project.

(11) If the accounting in the separate analytical records kept for the Project has ended in a given calendar year with a surplus, i.e. if not all the funds provided to the Beneficiary or to another Participant for the relevant year have been used, the Beneficiary shall inform the Provider. If the Beneficiary (and the other Participant) is not interested in using the unspent funds in the following years of the Project, it shall inform the Provider and return the unused funds to the State budget as instructed by the Provider. At the end of the Project, the Beneficiary is obliged to return all unspent funds for the Project as a whole (including all other Participants) to the State budget as follows (at the same time, it is necessary to notify the payment in writing according to the disposition indicated on the Provider's website):

a) the Beneficiary, which is an organizational unit of the State or a local self-government unit, is obliged to return the unused Special-purpose Support to the revenue account of its founder;
b) other Beneficiaries return the unspent funds to the Ministry of Health's foreign funds account No 6015-2528001/0710.

(12) Pursuant to Section 13 of the Act, the Provider is obliged to carry out checks on the fulfilment of the Project's objectives, including checks on the use and utilization of the Support and on the effectiveness of the costs recognized under the Contract on the granting of Support or the Decision on the granting of Support, in the case of a Beneficiary who also submits documents on behalf of other Participants, including financial checks pursuant to Act No. 320/2001 Coll., on financial control in public administration and on amendments to certain acts (Act on financial control), as amended. The Beneficiary and the other Participant are obliged to allow the Provider to carry out the control and to provide the Provider with all the required cooperation.

(13) If during the audit deficiencies in the drawdown were found and in particular if there was an unjustified drawdown of the Special-purpose Support from the State budget, the Provider proceeds in accordance with special legal regulations (in particular the Act on Budget Rules), Act No.320/2001 Coll., on financial control in public administration and on the amendment of certain acts (Act on financial control), as amended, and Act No.

(14) The Beneficiary is obliged to notify the Provider in writing of the proceeds of the Project results obtained during the course of the Project, no later than 60 calendar days from the date on which the claim to such proceeds, stating the amount and the reason for it. In the sub-report or final report, the Beneficiary must indicate the total amount of all the Project proceeds achieved during the Project year and propose how they will be used in the Project. The proceeds of the Project results obtained after the end of the Project are:

a) revenue of the State budget if the Beneficiary is an organizational unit of the State;
b) revenue of the budget of a local self-government unit if the Beneficiary is an organizational unit of that local self-government unit;
c) the Beneficiary's yield for all other beneficiaries.

P8.4 Principles for Project Solution

(1) The Beneficiary is obliged to initiate and implement the Project in the manner and within the time limit specified in the Contract or Decision.

(2) The Beneficiary is obliged to document or present the results of the Project in a manner appropriate to the nature of the relevant scientific field and the nature of the Project. The results of the solution must be presented according to the types defined in the currently applicable Methodology for the Evaluation of Results. A publication can only be recognized as the result of a Project if it explicitly states that the work was carried out with the financial Support of the funder and the registration number of the relevant Project is also indicated, and in the case of dedication of one publication to several Projects, justification is required in the sub- or final report. In documenting the results of the Project, the Beneficiary shall proceed in accordance with the information contained in the Project proposal.

(3) All rights to the Project results belong to the Beneficiary in accordance with the provisions of Section 16 of the Act. The rights of the authors and originators of the results and the owners of the protection rights to them are regulated by specific legal provisions. The provisions of Section 16(4)(a) of the Act apply to the exploitation of the results

(4) The Beneficiary is obliged to deliver to the Provider by the annually announced deadline data on the results of all its Projects carried out with the Support of the Provider, which are intended for the information system of research, experimental development and innovation (part of the Index of information 130/2002 Coll. and Government Regulation No 397/2009 Coll, on the Information System for Research, Experimental Development and Innovation.

(5) The Beneficiary is obliged to inform the Provider in writing of any changes that have occurred during the course of the Project which could have any effect on the solution or which affect in any way its legal personality or the data required to prove its eligibility, no later than 7 calendar days from the date on which it became aware of such a fact.

(6) If it is found during or after the completion of the Project that the conditions of the Contract for the provision of special-purpose Support or the Decision to increase the budget have not been complied with, or that there has been a breach of the conditions under the Act, the provisions of Section 14 of the Act shall be followed

(7) The Beneficiary and the other Participant are obliged to keep all documentation relating directly or indirectly to the Project and its progress for at least 10 years after the end of the Project, in particular:

a) professional documentation for the Project;
b) documentation on the management of the Special-purpose Support granted;
c) accounting documents relating to the separate accounting records of the management of the Special-purpose Support granted;
d) contractual documents relating to the Project and its solution, including any amendments or additions thereto;
e) the results of the Project.

(8) The Provider shall keep the tender documents, including Project proposals sent to the to the public tender for a period of 10 years.

P8.4.1. Interim Project report

(1) The interim project report (sub-report) shall contain information on the progress of the Project so far, the results achieved and the management of the Grant for the period covered by the sub-report. Annexes, which shall always be specified, shall be attached as an integral part of the sub-report. The Provider is entitled to request additional documents related to the Project at any time. When completing the sub-report, the published instructions at www.mzcr.cz or www.azvcr.cz and the instructions in the application shall be followed. An **exception is the sub-report after the first year of the Project, where information on the progress of the Project so far is provided only in case of deviation from the timetable or the planned Project**.

(2) A sub-report must be prepared for each calendar year of the Project and must be delivered by the Beneficiary by the date specified on www.mzcr.cz or www.azvcr.cz. If, in exceptional cases, the Beneficiary is not able to prepare and submit the sub-report (or its

annexes) by the deadline for serious objective reasons, he/she must notify the Provider in writing before the deadline and state the reason why the sub-report cannot be submitted in due time. The Provider is entitled to decide to extend the deadline for delivery of the relevant sub-report.

P8.4.2. Final Project report

(1) The final report shall contain information on the results of the Project for the entire duration of the Project and on the results of the management of the Special-purpose Support for the last year of the Project.

(2) The Beneficiary is obliged to deliver the final report to the Provider no later than the date specified on the websites www.mzcr.cz and www.azvcr.cz. The final report must be accompanied by annexes, which will always be specified, as an integral part of the final report. The Provider is entitled to request further documents related to the Project at any time. When completing the final report, the published instructions on www.mzcr.cz or www.azvcr.cz and the instructions in the application shall be followed.

(3) The Beneficiary is entitled to request an extension of the deadline for submission of the final report by completing the Form Part ZO and submitting it within the time limit referred to in paragraph 2 of this Article together with those parts of the final report which can already be processed and delivered in final form.

(4) If the Support Contract has been cancelled by withdrawal or has ceased to be effective for any other reason, or if the Decision to grant Support has been revoked, the Beneficiary must draw up a final report and deliver it no later than 30 calendar days after the date on which the Support Contract ceased to be effective or the date of the Decision of the cancellation of the Decision to increase the budget. The Beneficiary's other obligations are not affected.

P8.4.3. Evaluation of the progress of the Project

(1) The evaluation of the progress of the Project is carried out annually by the Scientific Council of the AZV on the basis of the submitted partial reports and the results of the Provider's monitoring activities.

(2) The Provider shall evaluate the progress of the Project according to the following main criteria:

a) the progress of the work and its consistency with the fulfilment of the set objectives;
b) providing solutions in terms of expertise and personnel;
c) the use of technical and instrumental equipment acquired from the special-purpose Support provided;
d) achievement of the objectives of the solution in comparison with the plan set out in the Project proposal, assumptions of the overall time and material completion of the task;
e) evaluation of the current management of the Special-purpose Support provided, or the proposed budget for the next period (the use of the allocated funds, the effectiveness of their spending and compliance with their composition, proper justification of any transfers or changes);
f) assessment of results according to the types defined in the currently valid Methodology for the Evaluation of Research Results.

(3) If the prerequisites for the continuation of the Project are met and the Provider decides to continue to Support the Project, and if the conditions under Article 2 of this Annex are met, the Beneficiary shall be granted the Grant for the next year of the Project.

(4) If the prerequisites for the continuation of the Project are not fulfilled, the Provider is entitled to withdraw from the Support Contract or cancel the Decision to grant Support according to the provisions set out in the Contract or Decision.

(5) The Provider is entitled to reduce the Special-purpose Support in view of the Project's progress to date or in view of the results of the checks pursuant to Section 13 of the Act, in which case an amendment to the Contract on the provision of Special-purpose Support will be concluded or a Decision will be issued amending the original Decision on the provision of Special-purpose Support. When concluding an amendment or issuing a Decision, the procedure shall be similar to that set out in Article 1 of this Annex.

P8.4.4. Evaluation of the completed Project

(1) The evaluation of the completed Project is carried out by the Scientific Council of the AZV on the basis of the final report and the result of the audit activity on the management of the special-purpose Support provided. Each Project is evaluated separately.

(2) The results of the evaluation of completed Projects are published by the Provider on its website for the year in aggregate.

(3) During the final evaluation of projects after their completion, the Provider shall, in accordance with Section 13 (4) of the Act, assess the results of the set out objectives in accordance with Article 5.7 of the TD, their relationship to the project objectives and provide information about them into the information system of research, experimental Development and innovation data according to Government Regulation No. 397/2009 Coll., on the Information System of Research, Experimental Development and Innovation. The basic evaluation categories are as follows:

- **V** = outstanding Project results (of international significance, etc.), meaning, the Project objectives and expected results as stated in the Contract of the Grant/budget increase Decision were met;
- **U** = succeeded according to the assignment, i.e. the Project objectives and its expected results as specified in the Grant Contract/budget increase Decision were met;
- **O** = assignment not fulfilled, but Contract/Decision conditions were complied with;
- **S** = assignment not fulfilled, the penalty provisions of the Contract/Decision have been invoked.

The Project Investigator whose final report has been evaluated in the "S" category is not awarded the Special-purpose Support of the MoH for the following 3 years (from the date of this evaluation, not from the end of the Project) and is therefore excluded from participation in further public tenders of the MoH during this period.

P8.5. Changes during the course of the Project’s solution

(1) The Beneficiary and the other Participant are not entitled to deviate from the status resulting from the concluded Grant Contract/budget increase Decision, including the approved

Project proposal that forms part of the Contract or Decision. Any changes to the Contract or Decision must be supported by a valid and effective amendment to the Contract or a new Decision.

(2) In the course of the Project design, changes may be made from the originally approved Project design only in the following cases:

a) A change in the eligible costs or a change in the amount of Special-purpose Support granted;

b) Change of another Participant, Investigator or Co-investigator of the Project.

(3) Changing the objective, the subject of the Project and the Beneficiary is not allowed.

(4) Transfers within the other operating costs or within the personnel costs of the Support allocated under Article 3 of this Annex, and changes in the Investigator team, except for changes in the Investigator or Co-investigator or other Participant (including changes in the level of their time commitment), are possible without an application and without the need for an amendment to the Contract or a new Grant Decision. However, in the following report (partial or final), the Beneficiary must provide a TD-rationale in the Justification section, Justification of the TD-distribution, respectively. It must demonstrate that the changes or transfers were efficient, cost-effective, effective and justified by the approved activities and that they meet the conditions for Support set out in Act No 130/2002 Coll. and the Tender Documentation. If the Beneficiary does not duly demonstrate the justification of the changes or transfers in accordance with the previous sentence, the Provider has the right not to recognize them and to apply the penalties provided for in the Contract or Decision.

(5) The procedure in paragraph (4) does not allow for a transfer or request for a transfer to the additional (overhead) costs item referred to in Article 5.4.3, paragraph (7) of the TD. The Beneficiary or other Participant is obliged to use the personal costs intended exclusively for students for personal costs intended exclusively for students.

(6) Transfers between items of the basic composition (other operating costs and personnel costs) of the appropriations referred to in Article 3 of this Annex, up to a maximum of CZK 100 000 may be made without a request and do not require an amendment to the aid contract or a new decision on a budget increase (i.e. CZK 100 000 per year per project for all Participants). In the event of a change in the generally binding legal regulations concerning personnel costs in the project (e.g. changes in salary tariffs, changes in the compulsory contribution to the FKSP, etc.) and their impact on the economic indicators, transfers can be made between individual items (from other operating costs to personnel costs) even above the limit of CZK 100 000 without a request and do not require an amendment to the Contract or a new Decision. However, in the following report (partial or final) the beneficiary must describe and justify these changes.

(7) Where the Beneficiary and the other Participant are entitled to constitute a designated fund or in the case of unspent designated funds, the provisions of paragraph (4) of this Article shall apply mutatis mutandis to their use.

(8) The amount of eligible costs and the related amount of Support provided for the Project for the entire duration of the Project may not be changed during the course of the Project by more than 50% of the amount of eligible costs or the amount of public Support specified in the Grant Contract or in the Decision on the budget increase, as decided by the Provider in the evaluation of the public tender. Changes to the amount of eligible costs and the related Support amount must be

justified, Supported by the approved activities and the amendment to the Support Contract or the new budget increase Decision and must comply with the Support conditions laid down in the law.

P8.5.1. Project change procedure

(1) If there is a substantial change in the circumstances relating to the Project which the Provider could not have foreseen and was not caused by the Provider, the Provider shall propose to the Beneficiary a change in the amount of eligible costs, a change in the amount of Special-purpose Support or an amendment to the Grant Contract or Decision the Beneficiary in writing within 7 calendar days of becoming aware of such a fact. The Beneficiary shall comment on the proposal in writing within 60 calendar days of the date of receipt of the proposal.

(2) If there is a substantial change in the circumstances relating to the Project which the Beneficiary could not have foreseen or was not caused by the Beneficiary, the Beneficiary shall request the Provider to change the structure or amount of the eligible costs, to change the amount of the Special-purpose Support or to amend the Contract granting the Support or the Decision to increase the budget in writing, no later than 7 calendar days from the date on which it became aware of such a fact. This obligation is also fulfilled by sending an information letter to before sending the application form for approval of the change in the Project. If the amendment concerns a change in the financial means of the Support granted in a given calendar year, it must be submitted no later than 60 calendar days before the end of that calendar year. However, the Provider is not obliged to accept or agree to such a change in the structure or amount of eligible costs or in the amount of Special-purpose Support. If the change concerns an extension of the duration of the Project (only within the duration of the Program), the request for change must be submitted no later than 90 calendar days before the end of the Project.

(3) If the Provider agrees with the Beneficiary's request made under paragraph (2) of this Article, it shall conclude an amendment to the Contract for the provision of Special-purpose Support with the Beneficiary or issue an amendment Decision on the increase in the budget within 60 calendar days of the date on which it received the request. If the Provider rejects the Beneficiary's application under paragraph (2) of this Article, it shall notify the Beneficiary of this fact by written communication within 30 calendar days of the date of the examination of the application; no Decision on the application shall be issued.

(4) A request for changes in the Project design must include the following:

a) identification details of the Beneficiary, the Investigator (or other Participant and Co-investigator if there is a change concerning another Participant) and the Project concerned, including the registration number;
b) specifications of the requested change;
c) a detailed description of the reason and justification for the requested change;
d) an indication of the time when the cause of the requested change occurred;
e) the signatures of the Beneficiary, or the person authorized to act for the Beneficiary, and of the Investigator (and, where appropriate, of the other Participant and the Co-investigator if the change concerns another Participant).

P8.5.2. Procedure for changing another Participant, Investigator or Co-investigator

(1) If the Investigator is unable to continue the Project at the Beneficiary's workplace specified in the Contract for the provision of special-purpose Support / Decision on the budget increase for a serious reason, the following procedure shall be followed:

- the Beneficiary asks the Provider, in accordance with the procedure set out in Article 5.1 of this Annex, for a change in the Project design consisting in the appointment of a new Investigator; the professional qualifications of the new Investigator must be Supported by a curriculum vitae, as in the case of a Project Proposal.

(2) If the Provider accepts the Beneficiary's request under paragraph (1) of this Article, the procedure in Article 5.1(3) of this Schedule shall continue to apply, provided that if the Beneficiary's draft amendment the Provider shall be entitled to withdraw from the Support Contract. A similar procedure shall be followed in the event of a new Decision to increase the budget.

(3) If the Co-investigator cannot continue the Project for a serious reason at the workplace of the other Participant specified in the Contract for the provision of special-purpose Support, or in the Decision to increase the budget, the following procedure shall be followed:

(a) the Beneficiary requests the Provider in accordance with the procedure similar to that set out in Article 5.1 of this Annex for a change in the Project design consisting in the appointment of a new Co-investigator; the qualifications of the new Co-investigator must be supported by a curriculum vitae as in the Project Proposal; or

(b) the Beneficiary requests in writing to the Provider the transfer of rights and obligations in the Project to another additional Participant who is a new site of the Co-investigator; this request must include the written consent of the original Beneficiary, the new proposed additional Participant

to such a procedure, bearing their signatures or the signatures of the persons authorized to act for them in this matter, and the eligibility of the proposed other additional Participant must be demonstrated in accordance with Article 4.2 of the TD.

(4) If the Provider accepts the Beneficiary's request under paragraph (3)(a) of this Article, the procedure shall be as set out in Article 5.1(3) of this Annex, provided that if the Beneficiary rejects the draft amendment to the Support Contract, the Provider shall be entitled to withdraw from the Support Contract. A similar procedure shall be followed in the event of a new Decision to increase the budget.

(5) If the Provider accepts the Beneficiary's request under paragraph (3)(b) of this Article, the rights and obligations for the Project shall be transferred from the existing additional Participant to the new additional Participant by a separate tripartite Contract between the Beneficiary, the existing additional Participant and the new additional Participant. At the same time, an amendment to the Support Contract shall be concluded between the Provider and the Beneficiary. If the Beneficiary proposes an amendment to the Contract Support Contract is rejected, or the original or new additional Participant rejects the draft tripartite Contract on the transfer of rights and obligations in the Project, the Provider is entitled to withdraw from the Grant Contract. A similar procedure shall be followed in the event of a new Decision to increase the

budget. A Contract between the Beneficiary, the existing additional Participant and the new additional Participant on the settlement of the assets acquired with the funds during the course of the existing Project, concluded between the existing additional Participant and the new additional Participant, shall form an integral part of the tripartite Contract between the Beneficiary, the existing additional Participant and the new additional Participant. If the existing and the new additional Participant do not reach an agreement, the Provider is entitled to withdraw from the Support Contract.

(6) If the Provider does not comply with the Beneficiary's request under paragraph (3) of this Article, it may withdraw from the Support Contract or cancel the Decision to Grant Support. The Beneficiary shall then be obliged to reimburse any unused Support after a proper accounting.

Annex 9 – Project Proposal Evaluation Process

The Ministry of Health (MoH) has established the AZV, which is an organizational unit of the State under the direct competence of the MoH, and the tasks of the AZV include, among others, ensuring the evaluation of Project proposals.

The evaluation process meets the following conditions (specified in more detail below):

- the statutory assessment period;
- a three-tier evaluation system:
  - the Decision-making body is the Provider, which acts on the proposal of the AZV Board in accordance with the AZV Statutes;
  - the Scientific Council of the AZV is a professional advisory body according to the law;
  - the Evaluation Panels are expert bodies of the Scientific Council of the AZV.
- the statutory number of at least two independent assessments for each Project proposal accepted for peer review;
- for Projects advancing to the second stage of assessment, two additional external assessments (one foreign and one domestic (including SR));
- Participants in the evaluation process are bound by the obligation of confidentiality.

P9.1. First level of evaluation

The first phase

(1) Each Project proposal is assigned for review by two members of the Evaluation Panel – correspondents (in the case of interdisciplinary Projects, a third correspondent from the adjacent Evaluation Panel is also assigned). The Chairman together with the Vice-Chairman of the Evaluation Panel shall designate the first correspondent for each Project proposal, the second correspondent being selected at random.

(2) The correspondents will study the Project proposal and each independently prepare their own opinion.

(3) Each of the correspondents shall independently and objectively evaluate each of their assigned Projects verbally and assign a score of 0-100 to each of the Project proposals assigned to him/her through the electronic application according to the criteria for the evaluation of Project proposals.

(4) The members of the Evaluation Panel shall not communicate in any form to the other members of the Evaluation Panel information about the Project proposals under consideration or their evaluation until three days before the meeting of the Evaluation Panel, when the evaluations are published to all members of the Evaluation Panel.

(5) Each member of the Evaluation Panel shall, three days before the meeting of the Evaluation Panel, have access via an electronic application to all Project proposals from his/her Evaluation Panel, with the exception of his/her own Project proposal and Project proposals for which he/she has a conflict of interest.

(6) Each of the two correspondents assigned to a given Project proposal will recommend 2-3 suitable foreign referees and 2-3 suitable domestic external referees for the Project proposals.

Panel evaluation in the first phase

(1) At the Panel meeting, the Panel will review the judgments of the individual correspondents for each Project proposal and assign a score of 0-100 for the Panel to the Project proposal. Based on a predetermined algorithm, the application will produce a ranking from the highest value (highest scoring Project proposal) to the lowest (lowest scoring Project proposal). From this ranking, the Panel discussion produces a list of at least 30% of the lowest ranked proposals from all Project proposals considered in the Evaluation Panel that are not recommended for the second phase, and therefore will not be sent to foreign or domestic external referees for evaluation.

(2) The Evaluation Panel, on the basis of the recommendations of the correspondents, will further decide on the assignment of external domestic and foreign referees for the Project proposals that will proceed to the second phase of the evaluation.

(3) The Evaluation Panel will submit the following materials to the AZV Scientific Council for each Project proposal:

- the minutes and protocol of the Evaluation Panel's proposal for the elimination of the individual lowest-ranked Project proposals, including the reasons for their evaluation;
- the opinions of two or three correspondents;
- proposals by correspondents on foreign external referees;
- proposals by correspondents for domestic external referees.

Evaluation in the Scientific Council of the AZV in the first phase

(1) Prior to the meeting, the members of the Scientific Council of the AZV shall become acquainted with the minutes of the meetings of the Evaluation Panels, the reports of the correspondents, the data on the scoring of the Project proposals by the correspondents and the proposals for foreign referees and Czech external referees.

(2) The members of the Scientific Council of the AZV will discuss the proposal of the respective Evaluation Panels on the evaluation of individual Project proposals and recommend a list of Project proposals to be forwarded to the second stage of the assessment, and shall draw up a report on this.

(3) The recommendations of the Scientific Council shall be confirmed by the Board of the AZV after discussion. The Office will send the selected Project proposals recommended for advancement to the second phase of evaluation to external domestic and foreign referees.

The second phase

(1) One opinion on the Project proposal is obtained from a foreign referee and one opinion on the Project proposal from a domestic external referee (if more than one opinion is obtained on the Project proposal, the first opinion received will be taken into account in the evaluation in the order in which the opponents were contacted).

(2) Prior to the meeting of the Evaluation Panel, all members of the Panel shall be familiar with the following documents for all Project proposals that have advanced to the second stage of the evaluation:

- two evaluations from the Evaluation Panel, or a third in the case of interdisciplinary Projects, the Panel's score from the first phase of the evaluation,
- one review report from a foreign referee,
- one review report from a domestic external referee

(3) The application will produce a ranking of Project proposals according to the scores from the first phase and the scores of the referees, which will be discussed at the Panel meeting in the second phase.

Panel evaluation in the second phase

(1) First, the correspondents of each Project proposal shall present the individual Project proposals in turn.

(2) After detailed discussion and justification, the Evaluation Panel may change the final score for individual Project proposals by ± 20%. A necessary condition for the application of the ±11 to 20% correction is that at least one of the assessments is significantly out of line with the others, and this correction must always be duly and substantially justified by the Panel.

(3) Next, a ranking of individual Project proposals is created from the highest value (the highest scoring proposal) to the lowest (the lowest scoring Project proposal).

(4) For all Project proposals that have advanced to the second stage of evaluation, the Evaluation Panel shall carry out an economic evaluation of the Project proposals.

(5) In the **economic evaluation**, i.e. the evaluation of the proposed eligible costs the following shall be assessed:

a) the reasonableness of the proposed eligible costs in relation to the Project proposal and the expected results;
b) the level of specification and justification of the individual items of recognized costs;
c) the proportion of the funding requested from the Provider to the total proposed eligible costs (i.e. the proposed Support intensity);
d) compliance with the requirements for the scope and definition of eligible costs as set out in Article 5.3(6) to (9) and Article 5.4 of the SO;

(6) The Evaluation Panel shall draw up a report in which it shall propose to the Scientific Council of the AZV whether to accept the proposed Project costs, or to accept only part of the proposed costs, including the reason for not accepting that part of the Project costs, or propose to exclude the Project from the public tender, including the reason for such exclusion.

(7) In the event of the submission of an exceptionally costly Project proposal, such a proposal may be submitted to the Audit Board of the AZV for consideration, which will assess the adequacy of the costs envisaged in the Project proposal.

(8) The course of the entire meeting is recorded in the minutes, which serve as the basis for the Project evaluation protocol.

(9) At the conclusion of the meeting, the opinion of the Evaluation Panel and the ranking shall be entered in the evaluation record for each Project after it has been accepted by vote of the members of the Evaluation Panel.

P9.2. Second level of evaluation

(1) The second level of evaluation takes place at the level of the Scientific Council of the AZV. At this stage, the Scientific Council of the AZV will consider the evaluation of the Projects by the individual Evaluation Panels and approve the Project proposals, including their economic evaluation and ranking. Furthermore, the Scientific Council will agree on the allocation key. The proposals of the AZV Scientific Council are submitted to the AZV Board.

P9.3. Third level of evaluation

(1) Taking into account the proposals of the AZV Scientific Council, the AZV Board will prepare a draft final Decision on the funding of Projects for the Provider.

(2) The Provider shall decide on the granting or refusal of Special-purpose Support in a public tender. In accordance with the law, it may also decide contrary to against the recommendation of the Provider's expert advisory body (the AZV Scientific Council), provided that it gives reasons for its Decision in writing in the minutes and makes it public.

(3) The Provider shall publish its Decision on the evaluation and selection of Project proposals for funding on the Provider's website no later than the last day of the evaluation period.

(4) The Provider informs the Applicant of the result of the evaluation of its Project proposal by publishing the MoH Decision on the result of the public tender. Within 30 calendar days from the announcement of the results, the Provider shall make the result of the evaluation of all Project proposals in the public tender in research, development and innovation available to the public via the ISVP application, including the justification and **provision of anonymized reviews of correspondents and external Project referees, the indication of the score given by the Panel in the first phase of the evaluation and its justification, as well as any correction made by the Panel in the second phase of the evaluation and its justification**.

(5) If the Provider has reduced the proposed amount of eligible costs, the Applicant is informed in writing of the amount of eligible costs and is asked whether he/she will be able to carry out the Project with the reduced eligible costs (i.e. with the reduced Special-purpose MoH Support). If the Applicant refuses, the Provider will proceed in the same way as in the case of non-contracting, i.e. it will approach the Applicant who ranked first among the Projects not proposed for Support. If the Applicant agrees, it shall be asked to supply the modified data necessary for the conclusion of the Contract or the issuing of the Decision to Support the Project in order to meet the deadlines set for the conclusion of the Contract or the issuing of the Decision to grant Support.

(6) After the Beneficiary fulfils the TD and the conditions set out by law, the Provider will administratively prepare the Contract or the Decision and ensure the conclusion of the Contract or the issuance of the Decision within 60 days of the announcement of the results of the public tender (see TD Annex 8 for details). The condition for the release of Support to the Beneficiary and to another Project Participant by way of the Beneficiary in a joint Project is the submission of data on the Project to the Information System for Research, Development and Innovation – CEP.

(7) The Provider shall comply with its statutory information obligations to the Research and Development Council and other relevant administrative authorities.