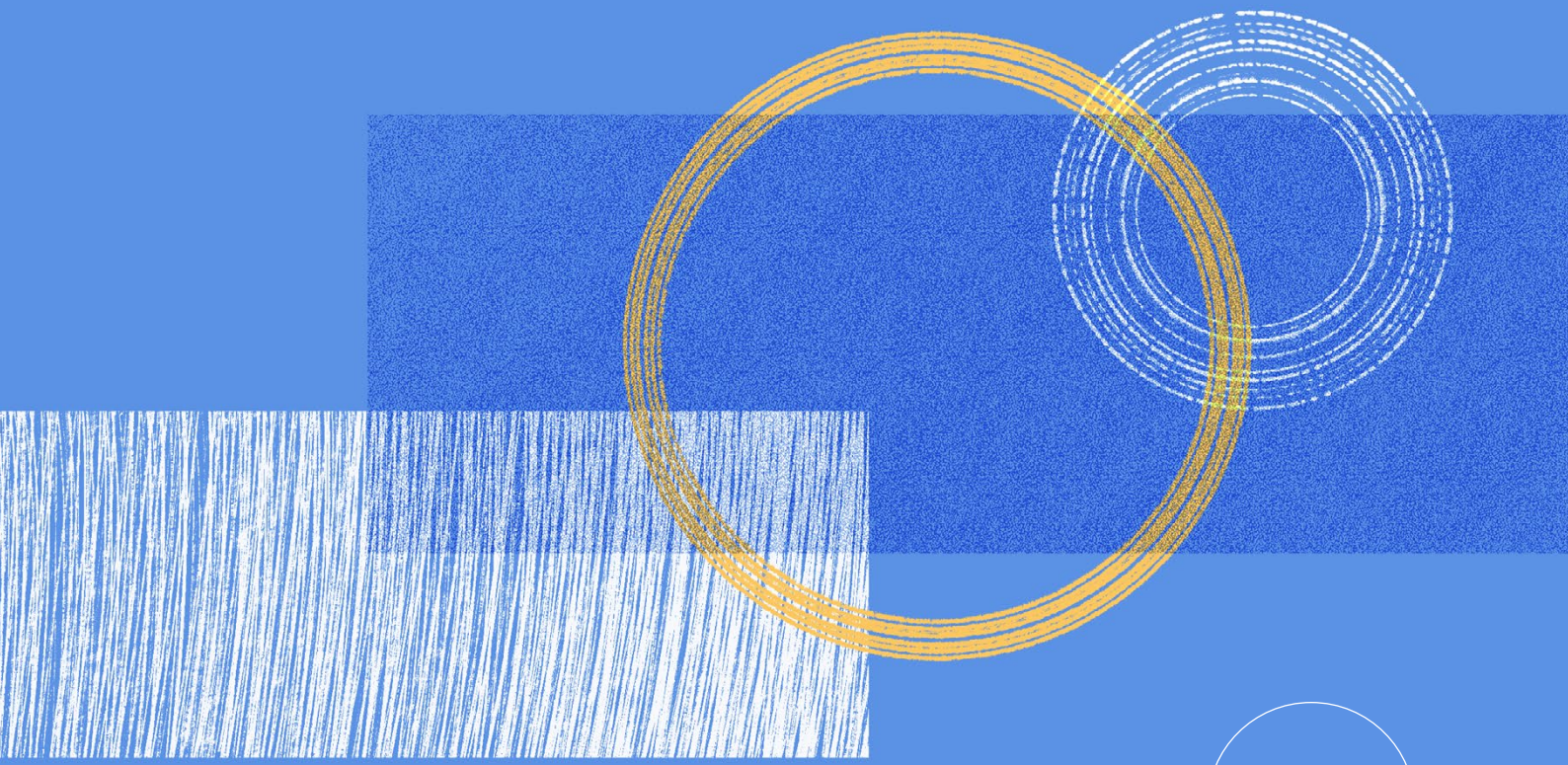
AZV ČR AGENTURA PRO ZDRAVOTNICKÝ VÝZKUM ČESKÉ REPUBLIKY

MINISTERSTVO ZDRAVOTNICTVÍ ČESKÉ REPUBLIKY

# GENERAL RULES

# OF PROGRAMMES OF THE MINISTRY OF HEALTH TO SUPPORT APPLIED MEDICAL RESEARCH



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# I. Introduction

## 1. BASIC INFORMATION

(1) These General Rules are issued by the Provider, which is the Ministry of Health of the Czech Republic, with its registered office at Palackého náměstí 375/4, 128 00 Prague 2, ID No. 00024341 (hereinafter referred to as the "Provider or the Ministry of Health") as an accompanying document for the announced public tenders.

(2) The Czech Health Research Council (hereinafter referred to as "**AZV**") is an organizational unit of the state under the direct management of the Ministry of Health of the Czech Republic. AZV is entrusted by the Ministry with the support of applied research in the health sector in accordance with the law, in particular by ensuring the evaluation of project proposals and the preparation of documents for the provision of special-purpose support, as well as the subsequent control of implementation.

(3) Public tenders are announced in accordance with Act No. 130/2002 Coll., on support for research and development from public funds and on amendments to certain related laws, as amended (hereinafter referred to as "the Act") and in accordance with Commission Regulation (EU) No 651/2014 of 17 June 2014, as amended by Commission Regulation (EU) No 2021/1237 of 23 June 2014. of 19 July 2021 declaring certain categories of support compatible with the internal market in accordance with Articles 107 and 108 of the Treaty on the Functioning of the EU[1] ("**Commission Regulation**") and in accordance with the Framework for State support for Research, Development and Innovation - Official Journal of the European Union of 19 October 2022 (2022/C 414/01) ("the **Framework**").

## 2. GLOSSARY OF TERMS

(1) **Application**

An online web application created for the ISVP application process at http://eregpublic.ksrzis.cz

(2) **Applied research**

According to the law, applied research means industrial research, experimental development or a combination thereof. The OECD Frascati Manual further defines applied research as original research carried out with the aim of obtaining new knowledge. However, it is primarily directed towards a specific practical purpose or objective. Applied research may be subdivided into basic research which is necessary to obtain the results of applied research.

(3) **Another participant**

Another project participant is an organisational unit of the State or an organisational unit of the Ministry engaged in research and development, as well as a legal entity or natural person whose participation in the project is defined in the project proposal and with whom the beneficiary has concluded a contract on participation in the project.

1 Published in the Official Journal of the European Union on 26 June 2014, 2014/L 187/01.

(4) **Intensity of support**

The support intensity is the proportion of the total eligible costs represented by the public support granted by the provider. The support intensity is set by the provider in accordance with the law, the Commission Regulation and the Framework.

(5) **Project proposal**

The project proposal is an application by the applicant for the provision of special-purpose support in the form of a grant or an increase in expenditure by an organisational unit of the State or a local self-government unit or an organisational unit of the Ministry engaged in research and development, in accordance with the budgetary rules. It must contain the information required by the DB and comply with the relevant legal provisions necessary for the granting of the support.

(6) **Proposer**

The proposer (or co-proposer) is the natural person who is responsible to the applicant (or co-proposer) for the professional level of the project proposal, must be in an employment relationship with the applicant (or co-proposer) (employment relationships based on agreements on work performed outside the employment relationship are not admissible), or such a relationship must have been established at the latest on the date of the start of the project and must last for the entire duration of the project. The only exception is if the applicant is a natural person, in which case the applicant is also the proposer. Each project proposal must include the name of the proposer (or co-proposer, as appropriate). The same natural person may act as proposer and co-proposer for only one project proposal in this call for proposals. The proposer (or co-proposer, as the case may be) becomes the principal investigator (or co-investigator, as the case may be) after the conclusion of the contract or the decision. Two types of project proposals can be submitted to this call for proposals:

a) Standard projects - only natural persons engaged in research who, at the time of submitting a project proposal to the call for proposals, hold an academic degree of Ph.D., its equivalent or higher (e.g. CSc., Dr., DrSc., DSc., etc.) may be a proposer;

(b) Junior Researcher Projects - only natural persons engaged in research who, in the year of submission of the project proposal to the call for proposals, meet the condition that no more than 8 years have elapsed since the award of the academic degree of Ph.D. or equivalent, which must have been obtained by the date of conclusion of the contract/ issuance of the project decision.

(7) **Patient organization**

A patient organization is a legal entity defined by Act No. 372/2011 Coll., on health services and conditions for their provision, as amended, which has, among other things, defined research activities as its subject of activity in its founding documents.

(8) **Enterprise**

Under the Commission Regulation, an enterprise is any entity engaged in an economic activity, regardless of its legal form. These entities include, in particular, self-employed persons and family businesses engaged in craft or other activities and companies or

associations regularly engaged in economic activities. The decisive factor in designating a beneficiary as an enterprise is whether it carries out an economic activity consisting of offering products or services on the market in question.

(9) **Provider**

The provider is the Ministry of Health of the Czech Republic, see point 2.3

(10) **Research project**

A research, development and innovation project (hereinafter referred to as 'project') means activities falling under one or more categories of support, intended to fulfil an indivisible task of a precise economic, scientific or technical nature with clearly defined objectives, formulated by the tenderer in a research, development and innovation call for tenders or by the provider in the context of a research, development and innovation contract award. The provider shall support a project proposal whose stated outcome is clearly aimed at healthcare applications.

(11) **Beneficiary**

The beneficiary is the applicant in whose favour the decision to grant support has been made by the provider. The beneficiary is responsible to the provider for the entire project (including the parts addressed by another project participant) in terms of its design, compliance with the eligibility conditions announced in this call for proposals, financial aspects, compliance with generally applicable regulations and provisions of the contract/ decision, the TD, the GR for projects under the general rules, including responsibility for any changes during the duration of the special-purpose support.

(12) **Investigation team**

The project team are individuals involved in the project. The team members are:

1. **The project Proposer** is a natural person who is responsible to the beneficiary for the project investigation from the labour law point of view and is responsible together with the beneficiary for the professional part of the investigation towards the provider of the special-purpose support.

2. **A co-applicant** is a natural person who is responsible to the beneficiary for the professional level of the part of the project provided by another project participant.

3. **An expert collaborator** is a natural person - an expert member of the researcher's or co-investigator's team, who is mentioned by name in the project proposal and participates in the project investigation.

4. **An additional staff member** is a natural person who assists in the project (e.g. support staff, technicians and administrative staff identified in the project proposal). Only the activities they provide and the scope of these activities (not by name) shall be mentioned in the project proposal.

(13) **Co-applicant**

A co-contestant in this public competition is a legal or natural person, an organisational unit of the State or a local self-government unit, an organisational unit of the Ministry, engaged

in research and experimental development, which is responsible to the tenderer for a part of the project proposal. The participation of the co-contestant in the project investigation must be defined in the project proposal, and the amount of the part of the special-purpose support that the co-contestant requires from the total state budget must be indicated. The co-applicant must be an entity distinct from the applicant (in the case of a legal entity with a different registration number).

(14) **Special-purpose support**

The special-purpose support for the project is provided in the form of a subsidy to legal or natural persons or an increase in the expenditure of organisational units of the State, organisational units of local self-government units or organisational units of the Ministry engaged in research and development, after a public competition has been held and evaluated and after the conditions laid down by law have been met. The special-purpose support is intended exclusively for the reimbursement of eligible costs.

(15) **Applicant**

The applicant is an organisational unit of the State or an organisational unit of the Ministry engaged in research and development, as well as a legal entity or a natural person applying for support.

(16) **Eligible costs**

Eligible costs are those eligible costs or expenditure in research, development and innovation which are approved by the provider and which are justified.

(17) **General rules**

The General Rules (also referred to as 'GR') contain information relevant to the tender and are publicly available on the Health Research Agency's website at the following link. Tenderers are required to refer at all times to the current version of the GQ available on the above-mentioned website.

(18) **Research organisation**

"Research and knowledge dissemination organisation" according to Commission Regulation (EU) No 651/2014, Article 2, point 83) means an entity (e.g. university or research institute, technology transfer agency, research-oriented innovation intermediary), regardless of its legal status (established under public or private law) or method of financing, whose **main objective is to carry out independently fundamental 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 of the funding, costs and income relating to those activities. Enterprises which may exercise decisive influence over such an entity, for example as shareholders or members, must not have preferential access to the results achieved by such an entity.

Before concluding a contract with the successful Applicant from this public tender, the provider will take into account the currently valid list of research organisations managed by the Ministry of Education, Youth and Sports of the Czech Republic.

(19) **Tender documentation**

The tender documentation (also referred to as "ZD") for the announcement of a public tender in research, experimental development, and innovation (also referred to as a "public tender") is a set of documents and information necessary for the preparation and submission of a project proposal within the meaning of Section 19 of the Act.

(20) **Eligible costs**

Eligible costs are those costs or expenditure in research, development and innovation which may be incurred by the beneficiary for, or in connection with, research, development and innovation activities and include in particular:

1. personal costs or expenses, including scholarships for research, development and innovation under the Higher Education Act,
2. the cost or expense of acquiring tangible and intangible assets,
3. other operating costs or expenses,
4. costs or expenses for services,
5. additional costs or expenses.

# II. Before signing the contract

## 3. DEFINITION OF DATA TO BE DISCLOSED

(1) For the purposes of the public tender and the fulfilment of other obligations, the provider is authorised to collect the necessary data on project proposals and applicants (co-applicants), including personal data, in accordance with the provisions of Section 17(6) of the Act and to fulfil the obligations under Section 32 of the Act. Both written and electronic forms of data collection are permitted. These data are not publicly available information.

(2) In collecting, processing and disclosing data, the provider is governed by specific legal regulations[2]. The scope of the data processed on project proposals and applicants is shown in the project proposal data. The project proposal data is identical to the data that the beneficiary of the grant is obliged to submit to the R & D & I - CEP.

(3) When the results of the public competition are announced, information about the projects is published on the Provider's website or on the AZV website, in the following scope: name of the beneficiary; name, surname, academic titles and scientific rank of the researcher; project title; programme title; programme code; application number; project duration; amount of special-purpose support granted.

(4) After the conclusion of the contract on the provision of special-purpose support or the issuance of the decision on the increase of the budget for the project, the data are published on the Provider's website or on the AZV website.

2 Act No. 110/2019 Coll., Act on the processing of personal data, 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 the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (hereinafter referred to as "GDPR")

(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.

## 4. PUBLICITY

(1) The publicity rules are listed on the Provider's and the AZV's websites; when presenting information about the project or its results, the Beneficiary is obliged to comply with the binding publicity rules in the current version published on the AZV's website.

## 5. PROGRAMME DIVISION INTO AREAS

### 5.1. Area 1 - Public health

**Sub-area 1.1: Socio-economic aspects of health**

Sub-objective 1.1.1: Collection, quality and application of data on health care and population behaviour

Sub-objective 1.1.2: Measure program impacts and analyze new programs or legislative proposals by government and independent experts

Sub-objective 1.1.3: Development of new methodologies and interdisciplinary collaboration in-health care

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

**Sub-area 1.2: Digitisation of health care**

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

Sub-objective 1.2.2: Digitisation will lead to improved accessibility and efficiency of health services and a higher level 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 change and care for the elderly**

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

Sub-objective 1.3.2: Analyse and address the social and health care needs of the elderly (especially the very elderly)

Sub-objective 1.3.3: Early prevention and mitigation of the impacts of invasive changes, including the use of modern technologies

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

**Sub-area 1.4: Health care**

Sub-objective 1.4.1: Analysis of the need for and use of health care among people with chronic diseases

Sub-objective 1.4.2: Measurability of health care outcomes
Sub-objective 1.4.3: Capacity, consumption and access to health care
Sub-objective 1.4.4: Human resources in the health sector
Sub-objective 1.4.5: Patients' participation rights and respect for their autonomy of will
Sub-objective 1.4.6: Means of protecting the rights of persons in health care 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 on specific target groups of the National Health Literacy Programme
Sub-objective 1.5.4: Research on specific areas of health literacy
Sub-objective 1.5.5: Competence of health professionals in health literacy
Sub-objective 1.5.6: Combat unscientific views in health care
Sub-objective 1.5.7: Strengthen 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.
Sub-objective 1.6.4. Chronic lung diseases
Sub-objective 1.6.5 Blood diseases
Sub-objective 1.6.6. Nervous and psychological diseases
Sub-objective 1.6.7 Musculoskeletal diseases and inflammatory and immunological diseases
Sub-objective 1.6.8. Addictions

**Sub-area 1.7: Global health**
Sub-objective 1.7.1: Environmental and work environment impacts on health
Sub-objective 1.7.2: Impact of nutrition and diet 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 occupational diseases
Sub-objective 1.7.6: Innovative approaches to health promotion and intervention programmes in primary prevention

## 5.2. Area 2 - Pathogenesis and development of diseases

**Sub-area 2.1: Metabolic and endocrine diseases**
Sub-objective 2.1.1: Etiology and pathophysiology of 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: To elucidate the aetiological factors and pathophysiological processes influencing the development and progression of cardiovascular (CVD) and cerebrovascular (CVO) diseases

Sub-objective 2.2.2: Developing early diagnosis of cardiovascular (CVD) and cerebrovascular (CVO) diseases and finding therapeutic modalities and procedures in the treatment of cardiovascular and cerebrovascular diseases with higher therapeutic efficacy and greater patient friendliness

**Sub-area 2.3: Cancer**

Sub-objective 2.3.1: Increase knowledge of cancer pathogenesis and development and identify new therapeutic targets

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

Sub-objective 2.3.3: Improve the quality of life of cancer patients through a better understanding of the factors associated with cancer and its treatment

**Sub-area 2.4: Chronic lung diseases**

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

Sub-objective 2.4.2: Establish new therapies by repurposing or combining 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: Increase knowledge of the pathogenesis and development of blood diseases and identify new therapeutic targets

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

Sub-objective 2.5.3: Improve 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 psychological 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: Increased effectiveness of treatments for diseases of the nervous system

Sub-objective 2.6.4: Ensure 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: Define the determinants of immunopathological diseases and identify new targets for the diagnosis and targeted treatment of these diseases

**Sub-area 2.9: Infectious diseases**

Sub-objective 2.9.1: Etiology and therapy of major infectious diseases
Sub-objective 2.9:2: Epidemiology of antimicrobial resistance
Sub-objective 2.9.3: New diagnostic methods
Sub-objective 2.9.4: New anti-infectives

**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

## 5.3. Area 3 - Innovative solutions for medicine

**Sub-area 3.1: Personalised medicine and new diagnostic and theranostic procedures**

Sub-objective 3.1.1: High-throughput molecular biology methods and bioinformatics tools for personalised 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: Personalised disease prevention
Sub-objective 3.1.5: Personalised treatment

**Sub-area 3.2: Low molecular weight drugs**

Sub-objective 3.2.1: New low molecular weight compounds
Sub-objective 3.2.2: Identify new therapeutic targets, new methods and procedures for biological testing

**Sub-area 3.3: Medicinal products for advanced therapies**

Sub-objective 3.3.1: Research and development of medicinal products for gene therapy
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 medicines
Sub-objective 3.3.4: Precision genomics as a tool for optimization and stratification of patients suitable for gene and somatic cell therapies
Sub-objective 3.3.5: Support proof-of-concept Phase I/II clinical trials to evaluate the safety and efficacy of medicines for advanced therapies
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, including prophylactic and therapeutic vaccines**
Sub-objective 3.4.1: New biological medicines
Sub-objective 3.4.2: New vaccines for the prevention and treatment of diseases

**Sub-area 3.5: New drug formulations**
Sub-objective 3.5.1: Development of novel carriers 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: Introduce new formulation technologies into research, development and production of dosage forms

**Sub-area 3.6: Research and development 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 conventional 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 performance
Sub-objective 3.7.3: Tissue and organ replacement
Sub-objective 3.7.4: Treatment procedures

**Sub-area 3.8: Telemedicine**
Sub-objective 3.8.1: Establish a data environment that enables the main objective to be met

**Sub-area 3.9: Innovative practices in palliative and supportive care**
Sub-objective 3.9.1: Effective organisation 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

## 6. PROOF OF ELIGIBILITY

(1) The following persons may be applicants for, or beneficiaries of, support from the Programme for a project under the Act, the Commission Regulation and the Framework, as well as co-applicants (or other participants) in the project:
- Research organisations, Patients organisations
- Enterprises

(2) As a natural person, only an entrepreneur who carries out an economic activity and at

the same time carries out a business activity pursuant to Act No. 455/1991 Coll., on Trade Enterprise (Trade Licensing Act), as amended, may be an eligible applicant.

(3) The assessment of whether the applicant or coapplicant fulfils the defining characteristics of a research organisation according to the Act, the Commission Regulation and the Framework will be carried out by the provider for each applicant or coapplicant individually during the evaluation of the project proposal, during the project and after its completion.

(4) In accordance with Section 18 (2) of the Act, the Proposer shall demonstrate **its eligibility** for the proposed project **by submitting a 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, and 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 the general rules;

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, with a copy of the business license or other required authorization (e.g., certificate of incorporation or other 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 (as per the TD Annex), 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 tenderer or its member (resp. 218/2000 Coll., with the exception of persons for whom conditions for the performance of the function of the statutory body or its member are laid down by another legal regulation (e.g. in the case of public universities and public research institutions); within the framework of the affidavit, the applicant/co-applicant shall also demonstrate compliance with the requirement pursuant to Section 14(3)(e) of Act No. 218/2000 Coll, on budgetary rules and on amendments to certain related acts, as amended (hereinafter referred to as the "Act on budgetary rules"), to be declared in ISVP.

d) if the project requires authorisation under a specific legal regulation or other proof (i.e. professional competence), all applicants (or coapplicants), regardless of legal form, must submit such authorisation or proof (a copy of the document is required as a minimum), by way of example:

- authorization according to Act No. 78/2004 Coll., on the handling of genetically modified organisms and genetic products, as amended (hereinafter referred to as Act No. 78/2004 Coll.), according to Act No. 285/2002 Coll., on the donation, procurement and transplantation of tissues and organs and on the amendment of certain acts (Transplantation Act), as amended (hereinafter referred to as Transplantation Act), according to Act No. 227/2006 Coll, on human embryonic stem cell research and related

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

activities and on amendments to certain related acts, as amended (hereinafter referred to as Act No. 227/2006 Coll.), all valid at least until the start of the project;

- authorization for the use of experimental animals (edited form acceptable) - 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., on the Protection of Animals against Cruelty, as amended (hereinafter referred to as Act No. 246/1992 Coll.), valid at least until the start of the project;
- permission to provide health services if the project will provide health services by an entity that is not a health care institution (e.g. University, Academy of Sciences of the Czech Republic);
- informed consent of the patient - if there is an experimental subject, the text of the informed consent of the patient/experimental subject who is aware of the risks and benefits of participation in the project and the possibility to withdraw from participation without consequences;
- the opinion of the ethics committee of the applicant/other participant on the currently submitted project proposal - see Article 7 of the TD;

e) the applicant must provide a document regulating the relationship of the project to the rules of SÚKL (original, certified copy or electronic conversion of the document):

- in the case of a project proposal that corresponds to a clinical trial of medicines, the applicant shall attach the Decision on the authorisation of the 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 proposal that corresponds to the conduct of a clinical trial of a medical device with a CE marking that will be used in the clinical trial outside the intended purpose of use and/or in the case of a project proposal that corresponds to the conduct of a clinical trial of a medical device without a CE marking, the applicant shall attach the Decision on Authorisation of the CP within the meaning of the Medical Devices and MDR Act (if such a clinical trial requires a Decision on Authorisation) or the Confirmation of Acceptance of the submitted notification (if the clinical trial requires a notification of the intention to conduct a clinical trial) within the meaning of the Act on Medical Devices and MDR Act. Medical Devices and MDR.

(5) The applicant with whom a contract is to be concluded for the provision of special-purpose support or in whose favour a decision on the budget increase is to be issued shall demonstrate the following **before the conclusion of the contract or, in the case of an organisational unit of the State, before the decision on the budget increase is issued**:

a) It is obliged 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 authorisation to operate.

c) The Provider shall also request the necessary cooperation from the Applicant in providing the data necessary for the submission of the request for an extract from the Criminal Records Register as required by law.

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 grant 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 details 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. The information referred to in points 1 and 3 is part of the affidavit attached to the TD.

e) If the nature of the project requires it, the applicant shall attach an officially certified copy of a valid document/authorisation for certain handling of genetically modified organisms and products (see Act No. 78/2004 Coll.), authorisation under the Transplantation Act, authorisation under Act No. 227/2006 Coll. In the case of a proposed project involving experimental work with animals, the applicant shall provide a **valid and effective 'experimental design'** 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 competent state authority, in accordance with Act No 246/1992 Coll – and Decree No 419/2012 Coll, on the protection of experimental animals, as amended - see general conditions.

f) If the nature of the project requires it, the tenderer shall attach a certified copy of the opinion of the ethics committee of the tenderer/other participant relating to this project – see Article 7 of the TD.

(6) If one tenderer submits more than one project proposal in a single call for proposals, it shall demonstrate its eligibility once, at the stage of submission of project proposals and at the stage before the signing of the support contract or the issuance of the decision to increase the budget under this TD.

(7) A tenderer with a seat outside the Czech Republic, who meets the conditions of Section 18 (11) of the Act, shall prove his/her eligibility according to Section 18 (2) (b) to (f) by means of an affidavit (a specimen of the affidavit is given in the TD Annex. In accordance with Article 1(5) (a) of the Regulation, the provider may require 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 a Proposer is obliged to prove, at the latest before the conclusion of the contract for the provision of support, 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 eligibility requirements under the provisions of Section 18 of the Act, similarly to a Proposer established in the Czech Republic.

(8) Eligibility must be demonstrated in full, i.e. for all requirements and for all persons for whom eligibility is demonstrated.

(9) Where a tenderer submits a project proposal with a co-tenderer, the obligation to demonstrate eligibility shall apply to the co-tenderer to the same extent as to the tenderer.

(10) According to the Commission Regulation, an enterprise which has been the subject of 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) cannot be a beneficiary or a participant[5].

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5 According to the Commission Regulation, Article 2(18), an 'enterprise in difficulty' is an enterprise where at least one of the following circumstances applies:
(a) In the case of a limited liability company (which is not an SME that has been in existence for less than three years, or, for the purposes of eligibility for risk finance support, which is not an SME within seven years of its first commercial sale, 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 the 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 to be the company's equity) is negative and exceeds half of the subscribed capital. For the purposes of this provision, 'limited liability company' includes in particular the forms of companies listed in Annex I to Directive 2013/34/EU and 'share capital' includes any share premium, where applicable.
(b) In the case of a company in which at least some of the shareholders are fully liable for the obligations of the company (which is not an SME that has been in existence for less than three years or, for the purposes of eligibility for risk finance support, which is not an SME within seven years of its first commercial sale that is eligible for risk finance investment on the basis of due diligence carried out by a selected financial intermediary), where the accumulation of losses has resulted in the loss of more than half of its capital as recorded in the accounts of that company. For the purposes of this provision, 'a company in which at least some of the shareholders are fully liable for the company's obligations' shall in particular be considered to be the forms of enterprises listed 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 firm has received rescue support 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 company's book debt-to-equity ratio is greater than 7.5; and
2) the interest coverage ratio of the company's earnings before interest, taxes, depreciation and amortization (EBITDA) is less than 1.0.

# 7. OPINIONS ON THE PROJECT PROPOSAL

The following representations shall be made, where appropriate, in the form of an annex to the project proposal

## 7.1. Opinion of the ethics committee of the applicant/other participant

(1) The ethics committee's consent statement for a given project must always be submitted by the applicant or coapplicant to whom the legal obligation applies, i.e. in the case of (i) healthcare delivery, (ii) research with human subjects, and (iii) 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 herein expressly confirms the accuracy of the attached "Informed Consent of the Patient/Investigator" and is responsible for its compliance if Informed Consent is required under the relevant law. In addition, in the case of anticipated work with human beings, a statement from the Ethics Committee on the protection of human beings must be provided. The original of the consent statement, a certified copy or an electronic conversion must be provided at the time of conclusion of the Grant Agreement.

(2) If the applicant does not have an ethics committee, the ethics committee of the other participant or the Ethics Committee for Multicentre Trials pursuant to the Medicinal Products Act No. 378/2007 Coll.

## 7.2. Statement of the Expert Committee - Protection of Experimental Animals

(1) In the case of a proposed project that involves experimental work with animals, the applicant shall provide a **valid and effective "experimental project"** relating specifically 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 favour 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) The original, a certified copy or a document with electronic conversion must be presented when concluding the Support Agreement. If the name of the experimental project does not correspond to the name of the project, the Application for approval of the experimental project (minimum copy) will also be attached.

## 8. DIVISION OF EVALUATION PANELS ACCORDING TO THEIR PROFESSIONAL FOCUS

(1) The Provider has established ten expert evaluation panels of the Czech Agency for Health Research to which applicants will submit their project proposals (according to the professional focus of the project):

- P01 Metabolic and endocrine diseases
- P02 Diseases of the circulatory system
- P03 Tumour diseases
- P04 Neuroscience and mental health
- P05 Immune disorders and infectious diseases
- P06 Intensive, perioperative, and organ-focused medicine (gastroenterology, hepatology, nephrology, and others)
- P07 Rare diseases and disorders of childhood
- P08 Biomedical technologies
- P09 Public health and nursing
- P10 Musculoskeletal medicine

(2) The focus of the individual evaluating panels is as follows:

- **P01 Metabolic and endocrine diseases**
  Panel 01 deals with metabolic aspects from the fields of: endocrinology and diabetology, clinical biochemistry and clinical pharmacology, medical genetics, paediatrics, gastroenterology, nephrology, rheumatology and other fields of internal medicine.
- **P02 Diseases of the circulatory system**
  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 in order to improve the current diagnostic, therapeutic and preventive measures of cardiovascular medicine
- **P03 Tumour diseases**
  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 panel prefers innovative projects with the potential for real application in oncological practice. Research in this panel covers a multidisciplinary spectrum of diagnostic, surgical, radiation, medical and other methods used or potentially applicable in oncology. Research projects in personalised and precision oncology and rare cancers are also supported.
- **P04 Neuroscience and mental health**
  Panel 04 deals with applied research in the field of etiopathogenesis, prevention, early and innovative 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, as well as neurosurgical, neurotraumatological, neurooncological and neurorehabilitation issues, clinical neurophysiology and neuropsychology. Topics include the social aspects of nervous and psychiatric diseases and the organisation of the provision of health services to the nervous and psychiatrically ill.

- **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 Intensive, perioperative, and organ-focused medicine (gastroenterology, hepatology, nephrology, and others)**
  Panel 06 deals with organ failure and organ replacement, intensive care, resuscitation, perioperative and transplantation medicine, especially epidemiology, prevention, early detection, and the development of new therapies in these areas. Organ-specific research includes diseases of the kidney and urogenital tract, liver and gastrointestinal tract, respiratory system, ENT, eye and skin.
- **P07 Rare diseases and disorders of childhood**
  Panel 07 deals with diseases that are specific to newborns, children and adolescents, but also to the senile period, and meet at least one of the following criteria: 1. their typical course at this age is significantly different and therefore represents a general health problem, 2. the medical approach to these diseases in childhood, adolescence or senile period plays a leading role in the field, 3. they have a significantly higher incidence in the mentioned age groups, including rare and ultra-rare diseases. To study the impact of genetic and environmental factors on the etiopathogenesis and pathophysiology of major diseases of childhood, adolescence and the elderly. Development of non-invasive diagnostic methods for childhood, adolescent and elderly diseases and/or development of preventive procedures and therapeutic methods to improve the quality of life of sick children, adolescents and elderly. The panel also includes diseases of pregnancy and the perinatal period if they may result in fetal and neonatal harm.
- **P08 Biomedical technologies**
  Panel 08 focuses on the research and development of biomedical and pharmaceutical technologies that directly contribute to innovation in diagnosis and treatment through technological approaches. Key areas include: (i) advanced diagnostic and therapeutic technologies (development of new imaging techniques, innovations in molecular

diagnostics, personalised and precision medicine and pharmacological approaches), (ii) development of new biomaterials and technologies for tissue and organ replacement or regeneration (design and testing of biomaterials with specific medical applications, implementation of innovative (surgical) treatment techniques using these technologies), (iii) pre-clinical research towards direct application in clinical practice (experimental development and in vivo testing of innovative technologies in animal models, application of new technological processes or materials with clear potential for clinical use), and (iv) biomedical devices and software technologies including artificial intelligence tools (development of new devices (hardware) and software solutions supporting diagnosis, therapy or health monitoring, implementation of artificial intelligence and data-driven technologies in biomedical research as well as in diagnosis and therapy). The scope of Panel P08 does not include projects focused on pure basic research without a clear technological overlap, projects focused on disease research (e.g. cardiovascular, cancer) without the development of unique technologies or innovative diagnostic/therapeutic tools, or projects that do not represent the actual development of a new technology or therapy and that use existing methods outside their primary purpose (off-target approaches). These projects fall under panels targeting specific disease groups.

- **P09 Public health and nursing**
  Panel 09 deals with public health issues including preventive medicine, hygiene, epidemiology and nursing. In the field of preventive medicine, the panel 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, health protection and promotion and the protection of healthy living conditions. In the field of epidemiology, the study of the prevalence of diseases and health disorders affecting the whole population and the monitoring of factors that condition or influence this prevalence at the population level, 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 characterisation 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 tools, 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. The P9 panel also includes areas such as digitalization of health care, demographic changes, but also global health, etc. Research on communication, combating misinformation and different types of motivational campaigns are supported. In the field of nursing, the emphasis is on projects focusing on active processes to meet the biological, psychological and social needs of the sick and healthy person in their health care.
- **P10 Musculoskeletal medicine**
  Panel 10 deals with: trauma in children and adults, congenital disorders and acquired

diseases in children and adults, musculoskeletal tumours, metabolic, degenerative and inflammatory diseases of the musculoskeletal system, anatomy and biomechanics of the musculoskeletal system. These topics include research in the following areas: etiology, pathogenesis, clinical, laboratory, biomechanical, imaging, and therapeutics. The concept of the panel is based on the need to elucidate some of the unresolved congenital and acquired defects, as well as to address diseases associated with the aging population, particularly in the increase of injuries and degenerative diseases and tumors, and pathological fractures and traffic and sports injuries in the younger population.

## 9. METHODOLOGY FOR RECEIVING AND EVALUATING 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, in accordance with the AZV Statutes, acts on the proposal of the AZV Board;
  - » The Scientific Council of the AZV is a professional advisory body according to the law;
  - » The expert 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 reviews by foreign opponents;
- participants in the evaluation process are bound by the obligation of confidentiality.

### 9.1. Acceptance of project proposals

(1) The evaluation of the project proposals will start at the earliest on the day following the last day of the competition period.

(2) The evaluation of project proposals consists of (the evaluation process for project proposals is described in the General Rules):

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 competition period and is concluded by the decision of the provider on the acceptance of project proposals into the public competition or their exclusion;

b) an evaluation 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; it follows the provider's decision to accept or reject the project proposals and is carried out throughout 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 the proposed eligible and eligible costs - a check is carried out on the relevance and correctness of the proposed eligible and eligible costs included in the project proposals, both in terms of the scope and definition of eligible and eligible costs and the amount of the proposed eligible and eligible costs; it follows the decision of the provider to accept the project proposals in the public tender or to exclude them and ends with the preparation of the project proposal evaluation reports.

(3) The evaluation of the project proposals is completed with the announcement of the results of the call for proposals.

(4) The decision to accept project proposals into the public competition or to exclude them, and the decision of the provider to select projects for implementation, are not subject to Act No. 500/2004 Coll., the Administrative Code, as amended, within the meaning of Section 21(11) of the Act.

(5) The reception of project proposals is carried out by the Commission for the Reception of Project Proposals, which will evaluate the fulfilment of the conditions of the call for proposals:

a) compliance with the competition deadline - it is assessed whether the project proposal was submitted within the competition deadline;

b) method and place of submission of the project proposal - the assessment is whether the method of submission of the project proposal specified in the TD, the name and originality of the file, the name of the ISDS batch;[6]

c) completeness of the project proposal - it is assessed whether the project proposal contains all the specified parts according to Article 4.2 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 tenderer or co-tenderer;

e) compliance with the minimum amount of time of the researcher/co-researcher according to Part 3 of the TD;

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.

(6) If at any time during the call for tenders it is proven that the tenderer or co-tenderer no longer meets the eligibility conditions, this is a reason for the project proposal to be excluded from the call for tenders.

(7) 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., in the case of non-compliant project proposals, it will indicate the reason for the exclusion from the expert evaluation of project proposals.

6 information system for data boxes

## 9.2. Evaluation of the truthfulness and accuracy of the data in the project proposal

(1) The evaluation of the truthfulness and accuracy of the data in the project proposal is also aimed at checking that the data are not contradictory. The evaluation is carried out independently by the referees, the evaluation panels, the provider's expert advisory body, which is the AZV Scientific Council, and the AZV office staff throughout the evaluation period.

(2) In particular, the following are considered to be incorrect and false data:

a) The Proposal and Project Description section of Article 4.2(3) and (4) of the TD is in a language other than the required language;

b) in Part A of the project proposal pursuant to Article 4.2(6) of the TD, an incorrect indication of the tenderer's or co-tenderers' registration number, in Part B of the project proposal pursuant to Article 4.2(8) to (11) of the TD:

A. numerical data which are not in the prescribed currency or in the prescribed units;

B. the proposed support intensity does not correspond to the actual proportion of the funds requested from the provider in the total project cost;

C. the proposed funding is contrary to applicable law;

D. the proposed personnel costs do not correspond to the relevant staff capacities (full--time equivalents) or do not adequately respect the provisions in Part 3 of the TD;

E. the proposed costs are not specified in detail in Part B - Justification of financial items as per Article 4.2.11 of the TD,

c) Part D of the project proposal under Article 4.2(14) of the TD does not provide full information on other projects of the proponent and co-proponents,

d) in all parts of the project design:

1. adopted texts not supported by a bibliographic citation according to the TD;

2. information that is untrue or does not correspond to reality.

(3) In particular, the following is considered to be 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 investigation 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 professional level of project proposals** is carried out by the provider's expert advisory body - the **Scientific Council of the AZV** and its expert bodies, which are the **AZV evaluation panels**. The quality of the proposer, co-proposers and the composition of the research 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 research team**, the following is assessed in particular: the **ability and aptitude of the proposer, possible co-proposers and their collaborators, to tackle the project**, their professional

skills, their overall contribution to the field of science, with regard their track record in research and experimental 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 coapplicants; the integration of gender aspects of the research team (e.g. gender equality plan, gender equality measures in the HR Award, etc.) shall also be taken into account.

(6) For the quality of the project, it is assessed primarily:

a) **project focus and relevance** – the project focus is assessed in terms of whether it is in line with the support areas of the Programme, 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 project's research objectives 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 (exceptions 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; gender considerations for project proposals where this is thematically relevant; 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, feasibility of the schedule; sophistication of the risk analysis; pure validation studies or projects whose investigations are predominantly based on contracted research or paid services delivered by partners outside the research team will not be preferred for support.

(7) **Previous cooperation with the provider** – the results and modalities of the applicant's (and coapplicants') and proposer's (and co-proposers') projects with support from the provider (if any); any breaches of the rules by the applicant (and co-applicants) or the proposer and co-proposers) in the management of the dedicated 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.

## 9.3. Economic evaluation of project proposals

(1) The economic evaluation of project proposals is 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 design and expected results;

b) the level of specification and justification of the individual items of recognised costs;

c) the proportion of the funding requested from the provider to the total proposed eligible costs (i.e. the proposed support intensity);

d) meeting the requirements for the scope and definition of eligible costs.

(3) The provider's expert advisory body may suggest that the provider should disallow part of the costs/expenses proposed by the applicant for the project and not include them among the eligible costs of the project under the Act. In such a case, it shall propose to the provider a reduction in the total amount of targeted support requested. 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.

## 9.4. Reasons for eliminating a project proposal from the public tender

(1) Any violation or non-compliance with the conditions defined in the Terms of Reference shall be grounds for elimination of the project proposal from the tender pursuant to Section 21 (3) of the Act,

(2) Submission of a project proposal that has already received special-purpose support under the Act, or that is submitted duplicatively or multiple times in a given calendar year to all providers' public competitions, is grounds for elimination of the project proposal from the public competition.

(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 set out in the Budget Rules 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 reason for the elimination of the project proposal is also the fact that the project is submitted by a researcher whose project financed from the special-purpose support of the Ministry of Health was prematurely terminated due to failure to fulfil the obligations set out in the project agreement. These are projects that have been stopped in the last 3 years.

(5) The project Proposer 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 competitions of the MoH during this period.

(6) The annexes to the project proposal cannot be documents that extend the annex "description of the project" (see Article 4.2 (4) TD).

# III. After the contract is signed

## 10. CONDITIONS FOR PROJECT INVESTIGATIONS

### 10.1. Procedure for concluding a contract for the granting of special purpose support or for issuing a decision on a budget increase

(1) The time limit and 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 the decision on the acceptance of the project proposal for the project. A draft contract is drawn up or, for the beneficiary organisational unit of the State or organisational unit of the Ministry, the provider issues a decision on the budget increase and implements a budget measure in accordance with the budget rules; the contract or decision sets out the binding conditions for the provision of the special-purpose support and the obligations of the beneficiary and the researcher.

(2) Failure to comply with the deadline set by the provider for concluding the contract for the provision of special-purpose support or for issuing 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 tenderer in the order resulting from the results of the public tender or to issue a decision to increase the budget in favour of such tenderer.

(3) The beneficiary is entitled to accept or reject the draft contract in its entirety 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, on the contrary, 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 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. 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 is 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 organisational units of the State under the competence of one administrator of the budget chapter, they do not provide each other with cash benefits and the provider shall define their mutual relations in the decision on the budget increase.

(6) If one or more additional participants will be involved in the project, the beneficiary shall be obliged to conclude a contract with each such additional participant within 30 calendar days

of the entry into force of the grant agreement for the project part, in accordance with the terms and conditions set out in the grant agreement, and to deliver such contract together with all annexes to the provider within that period; the contract shall be concluded for the entire period during which the additional participant is involved in the project.

## 10.2. Conditions, time limit and methods of granting special purpose support

(1) Unless the budget spending is regulated as a result of a budgetary provisional period under the Budgetary Rules Act, the provider will start providing special-purpose support for newly launched projects within 60 calendar days from the date of the contract's entry into force, or from the date of the decision on the budget increase. If an additional participant is involved in the project, special-purpose support may only be started 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 special-purpose support will start within 60 calendar days after the approval of the relevant partial report on project by the provider, provided that the conditions set out in the contract or decision are met. For ongoing projects, additional conditions must be met:

a) according to § 10 of the Act, the condition of inclusion of data in the information system of research, experimental development and innovation must be fulfilled;

b) where an amendment to the contract or decision on the granting of the specific support is to be concluded or issued for a given year, the amendment must take effect before the start of the granting of the specific support

(3) According to Section 10 of the Act, the provider provides special-purpose support only to the beneficiary by direct transfer to the beneficiary's bank account specified in the contract. If another participant, which is not an organisational unit of the State or an organisational 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 it on the basis of their mutual agreement, 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 organisational unit of the State or an organisational unit of the Ministry, the provider shall request the Ministry of Finance to implement the budget measure; the funds intended for this beneficiary or other participant shall be provided through the budget chapter of the respective founder.

## 10.3. Terms and conditions for the use of targeted 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. The special-purpose support granted in accordance with the contract or decision for the relevant calendar year must be accounted for in that calendar year. Any adjustments to the use of the special-purpose support for a given year may only be made in accordance with the conditions set out in the TD, the contract and the TD. Actions contrary to these conditions constitute a breach of budgetary discipline and are grounds for withdrawing from the contract or for issuing a decision to terminate the support and other sanctions under the Financial Regulation Act.

(2) The basic composition of the funds specified in the contract or decision must be respected when using the special-purpose support. 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 will 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 TA, the support disbursement and its composition is binding to two decimal places (CZK 0,01), regardless of the accuracy of the data presented in the sub-report or final report, 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.

(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 researcher; however, if it finds that these instructions are in breach of the regulations on the management of state property or that the funds are used in an inefficient, ineffective and uneconomical 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 credible data on the status of disbursement to the researcher 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 project concerned. The separate accounting records must always show the registration number of the project, all income and expenditure in that analytical account in 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 (interim and ex-post) the management of the special-purpose support during the project.

(6) The beneficiary shall submit to the provider in the partial or final reports a detailed overview of the use of the eligible 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 created 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 the provider an accounting of the subsidies provided to the beneficiary in the previous year (the beneficiary shall indicate the amount allocated to the provider's individual 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 can create an special-purpose fund) according to 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 on the granting of the special-purpose support and on the basis of a special agreement on the project part concluded between them, the part of the special-purpose support thus granted shall be managed by the other participant, who shall shall be obliged to comply with all obligations under that contract. The beneficiary shall in this case, the obligation to control also the management of the special-purpose support transferred to the other participant.

(9) If the beneficiary or other participant discovers during a given year of project implementation that there are facts requiring changes or transfers from the composition of the eligible costs or the special-purpose support provided in the contract or in the decision and its annexes, it is obliged to proceed in the manner set out in the DB and the general conditions.

(10) If the beneficiary or another participant is entitled to create a special-purpose fund on the basis of specific 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 has ended in the separate analytical records kept for the project 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 year in question have been used, the beneficiary shall inform the provider. If the beneficiary (and for the other participant) is not interested in using the unspent funds in subsequent years of the project, it shall inform the provider and return the unspent 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 organisational unit of the state or a local self-government unit, is obliged to return the unspent special-purpose support to the revenue account of its founder;

b) other beneficiarys 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 objectives, including checks on the use and utilisation of the support and the effectiveness of the recognised costs in accordance with the contract on the provision of support or the decision on the provision 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. 280/2009 Coll., Tax Code, as amended) and notifies the results of the audit to the locally competent financial office.

(14) The beneficiary is obliged to notify the provider in writing of the proceeds from the results of the project obtained in the course of the project, no later than 60 calendar days from the the claim to such income, 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 benefits from the results of the project 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 organisational unit of the state;

b) revenue of the budget of a local self-government unit if the beneficiary is an organisational unit of that local self-government unit;

c) the beneficiary's yield for all other beneficiaries.

## 10.4. Principles for project design

(1) The beneficiary is obliged to initiate and implement the project in the manner and within the timeframe 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 investigation must be presented according to the types defined in the currently applicable Methodology for the Evaluation of Results. A publication can only be recognised 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. If the practices in the field, the nature of the results and the conditions of the project allow it, it is appropriate to publish the results in Open Access form, or the publication outputs may be submitted to open digital repositories, in accordance with the licensing conditions of the publisher.

(3) All rights to the results of the project 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 shall 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 Register of information on results) in accordance with Act No. 130/2002 Coll. and Government Regulation No. 397/2009 Coll., on the information system of 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 project 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 terms 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 apply.

(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 investigation, including any amendments or additions thereto;

e) the results of the project.

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

## 10.5. Partial project report

(1) The sub-report shall be drawn up annually and shall contain information on the management of the special-purpose support granted for the period for which the sub-report is drawn up. The sub-report shall be accompanied by annexes, which shall always be specified, 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.mzd.gov.cz or www.azvcr.cz and the instructions in the application shall be followed.

(2) After the second year of the project, a partial report is submitted, expanding on the progress of the project so far and the results achieved, and the beneficiary is obliged to deliver it by the date indicated on the websites www.mzd.gov.cz and www.azvcr.cz respectively. 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.

(3) **An exception is the partial report after the first year of the project, where information on the progress of the project is only provided if there is a deviation from the schedule or the planned project investigation.**

## 10.6. Final project report

(1) The final report contains 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 indicated on www.mzd.gov.cz or 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.mzd.gov.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 Part LO form and submitting it within the deadline 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 to revoke the decision to increase the budget. The beneficiary's other obligations are not affected.

## 10.7. Evaluation of the project progress

(1) The evaluation of the progress of the project is carried out by the Scientific Council of the AZV, based on the assessment of the evaluation panel, on the basis of the submitted partial reports and the results of the monitoring activities of the provider.

(2) The provider evaluates 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 fulfilled and the provider decides to continue the project support, and if the conditions according to the TD and the GR are fulfilled, the beneficiary is granted the special-purpose support 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 targeted support in view of the project's progress to date or in view of the results of checks pursuant to Section 13 of the Act, in which case an amendment to the contract on the provision of targeted support will be concluded or a decision will be issued amending the original decision on the provision of targeted

support. When concluding an amendment or issuing a decision, the procedure shall be similar to that set out in Article 1 of this Annex.

## 10.8. 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 in a summary for the year.

(3) During the final evaluation of the projects after the completion of their investigation in accordance with § 13 (4) of the Act, the provider shall evaluate the achievement of the objectives set out in the contract on the provision of special-purpose support or in the decision on the budget increase, the results achieved by the project according to the TD, their relationship to the project objectives and provide information about them in 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 importance, etc.), which means that the project objectives and expected results as stated in the grant agreement/budget increase decision have been met
- **U** = succeeded according to the assignment, i.e. the project objectives and its expected results as specified in the grant agreement/budget increase decision were met;
- **O** = assignment not fulfilled, but contract/decision conditions have been complied with
- **S** = assignment not fulfilled, the penalty provisions of the contract/decision have been invoked.

(4) The project Proposer 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 competitions of the MoH during this period.

## 10.9. Changes in the course of the project

(1) The beneficiary and the other participant shall not be entitled to deviate from the status resulting from the concluded contract for the provision of special-purpose support/budget increase decision, including the approved project proposal which is 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 can 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 support granted;

b) change of another participant, investigator or co-investigator of the project.

(3) Changing the aim and object of the project is not allowed.

(4) Transfers within the other operating costs or within the personnel costs of the funds allocated under Article 10.3 of the TD, and changes in the research team, except for changes in the beneficiary, researcher or co-investigator (including a reduction in the amount of their time) or another participant, are possible without an application and do not require an amendment to the contract or a new decision to grant support. The same applies if a member of the research team who had the status of student leaves the research team. However, the beneficiary must justify these changes in the following report (partial or final) in the DB-Reasoning or ZB-Reasoning section. It must demonstrate that these changes or transfers were efficient, cost-effective, effective and supported by 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 recognise 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 listed in Section 10.3 of the TD. Personal expenses intended for students must be used by the beneficiary or other participant for personal expenses intended exclusively for students.

(6) Transfers between the items of the basic composition (other operating costs and personnel costs) of the funds allocated under Article 10.3 of the TD are possible without an application and do not require an amendment to the contract granting the support or a new decision to increase the budget (i.e. CZK 100 000 per year per project for all participants). In the event of changes to generally binding legal provisions concerning personnel costs in the project (e.g. changes to salary tariffs, changes to the mandatory allocation to the FKSP, etc.) and their impact on economic indicators, transfers between individual items (from other operating costs to personnel costs) can be made without an application and do not require an amendment to the contract or a new decision. However, the beneficiary must describe and justify these changes in the subsequent report (interim or final).

(7) In the event that the beneficiary and another participant are entitled to form a pool of special-purpose support, or in the case of unspent special-purpose support, the provisions of paragraph (4) of this Article shall apply mutatis mutandis to their disbursement.

(8) The amount of the eligible costs and the related amount of support granted 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 agreement or in the decision to increase the budget, as decided by the provider in the evaluation of the call for proposals. 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 issue of a new budget increase decision, and must comply with the support conditions laid down in the law.

## 10.10. 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 agreement or a 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. 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 and which 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 grant agreement 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 before the actual sending of the application form for approval of the change in the project. In case the amendment concerns a change in the financial means of the support provided in a given calendar year or an extension of the duration of the project (only within the duration of the Programme), the beneficiary must apply for the amendment no later than 60 calendar days before the end of the calendar year / before the end of the project. However, the provider is not obliged to accept or agree to such a change in the structure or amount of eligible costs or a change in the amount of special-purpose support.

(3) If the provider agrees with the beneficiary's request under paragraph (2) of this Article, it shall conclude an amendment to the grant agreement or issue an amending decision to increase the budget with the beneficiary within 60 calendar days from the date of receipt of 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) The request for changes to the project design must include the following:

a) identification details of the beneficiary, the investigator (or additional participant and co-investigator if there is a change concerning an additional 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 authorised 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).

## 10.11. Procedure for changing another participant, investigator or co-investigator

(1) If the researcher cannot 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 is followed:

- the beneficiary asks the provider, in accordance with the procedure similar to that set out in Article 10.1 of the TD, for a change in the project design consisting in the appointment of a new researcher; the professional qualifications of the new researcher must be supported by a curriculum vitae as in the submission of the project proposal.

(2) If the Provider accepts the beneficiary's request under paragraph (1) of this Article, the procedure under Article 10.1(3) of the TD shall continue, provided that if the beneficiary rejects the draft amendment to the grant agreement, the Provider shall be entitled to withdraw from the grant agreement. A similar procedure is followed in the event of a new decision to increase the budget.

(3) If the co-principal investigator is unable to continue the project at the other participant's site specified in the contract for the provision of special-purpose support or in the decision to increase the budget for a serious reason, the following procedure is followed:

a) the beneficiary requests the provider to follow a procedure similar to the change in the project design consisting in the appointment of a new co-leader; the qualifications of the new co-leader must be supported by a CV as in the project proposal, or

b) the beneficiary shall request the provider in writing to transfer the rights and obligations in the project to another additional participant, which is a new department of the co-organiser; an integral part of this request must be a written consent of the original beneficiary, the new proposed additional participant to such a procedure, bearing their signatures, or the signatures of persons authorised to act for them in this matter, and the eligibility of the proposed other additional participant must be demonstrated similarly according to the GR and the TD.

(4) If the Provider accepts the beneficiary's request under paragraph (3)(a) of this Article, the procedure under Article 10.1(3) of the TD shall continue, provided that if the beneficiary rejects the draft amendment to the grant agreement, the Provider shall be entitled to withdraw from the grant agreement. A similar procedure is 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 in 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 rejects the draft amendment to the support contract, or if the original or new additional participant rejects the draft tripartite agreement on the transfer of rights and obligations in the project, the provider is entitled

to withdraw from the support 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. 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 shall be entitled to withdraw from the support contract or to annul the decision to grant support. The beneficiary shall then be obliged to reimburse any unused support after a proper accounting.

## 10.12. Change of beneficiary procedure

(1) If, in exceptional cases, there is such a change in circumstances relating to the project that it is not possible for the beneficiary to continue the project and to achieve the corresponding project results, it is possible for the existing beneficiary, the new applicant and the project Proposer to apply jointly for a change of beneficiary. In addition to the requirements set out in the description of the project change procedure, the request for a change of beneficiary must in particular include:

- an affirmative declaration and a detailed justification of all the relevant facts justifying the application;
- a breakdown of the eligible costs of the project;
- the interim accounts of the project as at the date of the request for amendment;
- a description of the personnel, organisational and technical arrangements for the execution and progress of the work on
- the workplace of the new applicant at the time of the change of beneficiary;
- a proposal for a mutual settlement between the existing beneficiary and the new applicant, including both financial and property settlements and the settlement of the project results and rights to the research results;
- full proof of the new Proposer's full legal capacity;
- draft agreement on the assignment of the contract on the provision of special-purpose support pursuant to Section 1895 et seq. of Act No. 89/2012 Coll., the Civil Code, as amended

(2) The change of beneficiary must not change the content of the project according to the contract or the decision on the provision of the project support grant.

(3) The application will then go through an approval process, during which the new applicant must demonstrate that it meets all the legal requirements for eligibility under the public tender and that it is also able to provide the researcher and members of his team with adequate institutional and technical facilities for the project.

(4) If the provider accepts the application, the new applicant will enter into the legal status of the existing beneficiary by virtue of the assignment of the grant agreement. A similar procedure shall be followed in the event of a new grant decision.

(5) If the provider does not comply with the request, it is entitled to 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.


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