MEDICAL RESEARCH AGENCY

REGULATIONS OF THE OPEN CALL FOR RESEARCH EXPERIMENTS

CALL NUMBER: ABM/2026/3

RESEARCH EXPERIMENTS

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1. Glossary of terms

1) **MRA, the Agency**– Medical Research Agency;

2) **Clinical Study** – as defined in Article 2(2)(1) of Regulation (EU) No 536/2014 – means any research involving human subjects, the purpose of which is:

    a) the discovery or confirmation of the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;

    b) the identification of any adverse reactions to one or more medicinal products; or

    c) to investigate the absorption, distribution, metabolism and excretion of one or more medicinal products; with a view to ascertaining the safety or efficacy of those medicinal products;

3) **Clinical Trial** – means a clinical trial of a medicinal product or a clinical trial of a medical device;

4) **Clinical Trial of a Medicinal product** – within the meaning of Article 2(2)(2) of Regulation (EU) No 536/2014 – means a biomedical trial that meets any of the following conditions:

    a) the allocation of a participant to a particular treatment strategy is determined in advance and is carried out in a manner that does not constitute standard clinical practice in the Member State concerned;

    b) the decision to prescribe the medicinal product under investigation is made at the same time as the decision to enrol the participant in the biomedical trial; or

    c) in addition to standard clinical practice, participants undergo additional diagnostic or monitoring procedures;

The Projects of Clinical Trial for Medicinal products <u>are not eligible for funding</u> under this Call for Proposals.

5) **Clinical Investigation of *in vitro* diagnostic medical device** – as defined in Article 2(42) of Regulation 2017/746 – means a study undertaken to establish or confirm the analytical or clinical performance of the device;

Research Projects into the performance of *in vitro* diagnostic medical devices <u>are not eligible for</u> funding under this Call for Proposals.

6) **Clinical Investigation of Medical Device –** as defined in Article 2(45) of Regulation 2017/745 – means a systematic investigation involving at least one subject, undertaken to assess the safety or performance of the device;

The Projects of Clinical Trial for Medical devices <u>are not eligible for funding</u> under this Call for Proposals.

7) **Scientific research** – scientific research within the meaning of Article 4(2) of the Act of 20 July 2018 - Law on Higher Education and Science, conducted in the field of medical and health sciences, or interdisciplinary research combining at least two fields of science, one of which is the field of medical and health sciences;

8) **Non-interventional study** – within the meaning of Article 2(2)(4) of Regulation 536/2014, this refers to a biomedical study other than a clinical trial;

9) **Observational study** – a study conducted using non-interventional research methods (primarily in medicine and epidemiology), involving the monitoring of participants in their natural environment without the use of additional therapeutic procedures;

10) **Beneficiary** – an Applicant who has entered into a contract with the Agency for the implementation and co-financing of the Project (Article 3(2) of the Act);

11) **Rare disease** – a disease that affects no more than 1 in every 2,000 people in the population;

For the purposes of this Call for Proposals, a condition is not recognized as a Rare disease if the Orphanet database contains a note, alongside the assigned ORPHAcode, stating that it is not a Rare disease in Europe.

12) **CRO *(Contract Research Organization)*** – a natural person, enterprise, institution or organization to which the Beneficiary may, under a written contract, delegate some or all of its obligations or activities. Such a transfer shall be without prejudice to the Beneficiary's obligations, in particular with regard to the safety of participants and the reliability and robustness of the data obtained as part of the Research experiment;

13) **Pseudonymized data –** this should be understood to mean personal data processed in such a way that it can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is stored separately and is subject to technical and organizational measures that prevent it from being attributed to an identified or identifiable individual;

14) **Working days** – days from Monday to Friday, excluding public holidays and days designated by the Agency as non-working days, of which the Agency will notify the Applicant in good time. Whenever the Rules and Regulations refer to 'days' without specifying whether they mean working days or calendar days, such references shall be understood to mean calendar days;

15) **Research experiment –** within the meaning of Article 21(3) of the Act of 5 December 1996 on the Professions of Doctor and Dentist, a type of medical experiment aimed primarily at expanding medical knowledge. It can be carried out on both a sick and a healthy person. A Research experiment may be carried out provided that participation in it involves no risk, or that the risk is minimal and not disproportionate to the potential benefits of such an experiment;

16) **Medical experiment –** within the meaning of Article 21(1) of the Act of 5 December 1996 on the Professions of Doctor and Dentist, an experiment carried out on human subjects, which may be either a therapeutic experiment or a Research experiment;

17) **EMA** – this refers to the European Medicines Agency;

18) **GCP** – **Good Clinical Practice –** an international medical, ethical and scientific

standard for the planning, conduct, documentation and reporting of Clinical trial results, introduced by the International Council for the Harmonization of Technical Requirements for Registration of Medicinal Products for Human Use. Compliance with this standard ensures the protection of the rights and safety of research participants, as well as the reliability of the data obtained;

19) **Payment schedule** – this refers to a document setting out the reporting periods, the Projected amounts of advance payments or reimbursements, and the Projected dates on which these are to be paid to the Beneficiary;

20) **Research organization** – a university, a federation of entities within the higher education and research system, the Polish Academy of Sciences, operating pursuant to the Act of 30 April 2010 on the Polish Academy of Sciences, hereinafter referred to as 'PAN', a scientific institute of PAN, operating pursuant to the Act of 30 April 2010 on the Polish Academy of Sciences, a research institute operating pursuant to the Act of 30 April 2010 on Research Institutes; an international scientific institute established under separate Acts and operating within the territory of the Republic of Poland; any other entity primarily engaged in scientific activity on an independent and continuous basis; the Centre for Postgraduate Medical Education referred to in the Act of 13 September 2018 on the Centre for Postgraduate Medical Education, a healthcare provider established by a public medical university or a university conducting teaching and research in the field of medical and health sciences, or by the Centre for Postgraduate Medical Education;

21) **Milestone** – an event (not an activity) during the course of the Project. Reaching a milestone signifies the completion of an important stage in the Project schedule and necessitates a detailed review of progress and the justification for further work. Milestones should be measurable and should be linked to key (critical) deadlines within the Project that affect its future progress;

22) **Head of Research experiment –** within the meaning of Article 23(1) of the Act of 5 December 1996 on the Professions of Doctor and Dentist, a doctor holding a specialization in a field of medicine that is particularly relevant to the nature or

conduct of the experiment and possessing appropriately high professional and research qualifications.

In the case of a Research experiment involving a nonmedical component, the doctor in charge of the experiment shall collaborate with another person possessing the necessary qualifications to carry out the nonmedical component, who shall supervise the conduct of that component;

23) **Bioethics Committee** – this refers to an independent body authorized to issue opinions on proposed medical experiments, operating in accordance with the Regulation of the Minister of Health of 26 January 2023 on the Bioethics Committee and the Bioethics Appeals Committee;

24) **Call for Proposals –** this refers to the call for proposals announced and organized by the Agency for the implementation and co-funding of a Project under *the Open Call for Research Experiments ABM/2026/3* (Article 3(3) of the Act);

25) **Consortium Member –** an entity referred to in Article 17(1)(1, 2, 3, 5)(a) of the Act, which is not a natural person, contributing human, organizational, technical or financial resources to the Project, and implementing the Project jointly within the Consortium, on the terms set out in the Consortium Agreement. The Consortium Member shall carry out the Project in conjunction with the Consortium Leader and the other Consortium Members, including participating in the management and implementation of key tasks planned as part of the Project;

26) **Consortium –** a group of entities referred to in subsection 2.5.1 of the Rules and Regulations, established for the purpose of jointly implementing the Project, operating on the basis of the concluded Consortium Agreement, which substantially conforms to the model set out in Annex 3 to the Rules and Regulations;

27) **Consortium Leader –** the entity referred to in Article 17(1)(1, 2, 3, 5)(a) of the Act, not being a natural person, acting on its own behalf and on behalf of and for the benefit of the Consortium Members pursuant to an authorization/power of attorney granted to it in the Consortium Agreement: The Consortium Leader must

be the organization conducting the Research experiment proposed as part of the Project;

28) **Material** – Biological material, together with the questionnaire completed by a participant in a Research experiment, collected at a site funded by the Research Experiment Agency for the purposes of biobanking and conducting future scientific or research and development studies. The Material is stored in a biobank;

29) **Biological material** – Human tissue-derived material, defined as whole peripheral blood, collected as an additional sample in the course of a Research experiment funded by the Agency;

30) **Clinical Research Development Plan for 2020–2030** – a document setting out the objectives, priorities and directions for the development of clinical trials and the biomedical sector;

31) **Subcontractor –** an entity providing goods or services to the Beneficiary. A subcontractor may not be involved in the implementation of the Beneficiary's common financial policy or in the management of the Project. A subcontractor may not act as a party to the Consortium Agreement. The provisions of the Act of 11 September 2019 – Public Procurement Law – shall apply to the process of selecting a subcontractor, insofar as they relate to the Beneficiary;

32) **Polish Clinical Trials Network (PCTN)** – a specialist body established on 11 March 2021 through an agreement between the Agency and the beneficiaries of the first edition of the Call for proposals for the establishment and development of Clinical Trials Support Centres, with the aim of implementing uniform systemic quality and process solutions in organizations conducting clinical trials in Poland;

33) **Paediatric population** – the population aged between 0 and 18 years, including the following subgroups:

- the prenatal period of a child's development;
- preterm infants and full-term newborns aged between 0 and 27 days;

- infants (or young children) aged between 28 days and 23 months;
- children aged between 2 and 12, and
- teenagers aged 13-17;

34) **Experimental development –** development work within the meaning of Article 4(3) of the Act of 20 July 2018 – Law on Higher Education and Science, i.e. activities involving the acquisition, combining, shaping and utilizing currently available knowledge and skills, including in the field of IT tools or software, for the purpose of production planning and the design and creation of modified, improved or new products, processes or services, excluding activities involving routine and periodic changes made to them, even if such changes constitute improvements;

35) **President** – President of the Medical Research Agency;

36) **Medical Procedure –** within the meaning of Article 5(42) of the Act of 27 August 2004 on healthcare services financed from public funds, i.e. a diagnostic, therapeutic, nursing, preventive, rehabilitative or assessment procedure, taking into account the indications for its performance, carried out within the framework of a specific healthcare infrastructure using medicinal products and medical devices.

A Medical Procedure carried out as part of the Project must not be intended to assess the safety or efficacy of devices not bearing the CE marking or medicinal products not placed on the market in the Republic of Poland, but rather to assess the test method;

37) **Medicinal product –** within the meaning of Article 2(32) of the Act of 6 September 2001. Pharmaceutical law defines a medicinal product as a substance or mixture of substances presented as having properties for the prevention or treatment of diseases occurring in humans or animals, or administered for the purpose of diagnosis or for the restoration, improvement or modification of the body's physiological functions through pharmacological, immunological or metabolic action;

38) **Project** – the initiative described in the Grant Application relating to the

implementation of a Research experiment, submitted as part of this Call for Proposals. In the event of a recommendation for funding, the Project is then implemented by the Beneficiary on the basis of a Co-financing Agreement concluded following the outcome of the Call for Proposals, for a specified financial value, carried out within a set timeframe, and comprising the implementation of the tasks set out in the Grant Application;

39) **Protocol –** a document setting out the objectives, plan, methodology, statistical considerations and organization of a Research experiment. The term 'Protocol' includes subsequent versions of the Protocol and any amendments thereto;

40) **Endpoint reported by a Research experiment participant (REP)** – a result reported directly by a participant in the Research experiment and not interpreted by the observer. REPs may relate to the assessment of a participant's health status, quality of life or symptoms in a Research experiment**;**

41) **Head of the Application Evaluation Team –** a person appointed in accordance with Article 18(5) of the Act by the President from amongst the members of the Application Assessment Panel;

42) **Council –** Council of the Medical Research Agency;

43) **Reporting statement (Report) –** a document submitted by the Beneficiary for the purpose of accounting for expenditure incurred under the Project, in accordance with the Payment schedule. The report comprises a technical and financial report on the implementation of the Project and is drawn up by the Beneficiary;

44) **Final reporting statement –** the latest Progress Report submitted as part of the Project. The provisions of the Rules and Regulations relating to the Report/Interim Report also apply to the Final Report;

45) **Research Experiment Report** – an integrated, objective and structured document summarizing the course and results of the Research Experiment, drawn up in accordance with the guidelines set out in subsection 3.8.1 of the Rules and Regulations;

46) **Rules and Regulations** – these Call for Proposals' Rules and Regulations;

47) **Regulation 536/2014** – Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC;

48) **Regulation 2017/745** – Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC

49) **Regulation 2017/746** – Regulation (EU) 2017/746 of the European Parliament and of the Council on of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;

50) **Scientific risk –** the likelihood of failing to achieve the Project's objectives or targets, despite the Applicant and its collaborating entities acting in accordance with the law, the Agreement, applicable procedures and good practice, due diligence and the code of ethics for researchers, caused by circumstances that could not have been foreseen at the stage of applying for funding or by the obtaining of negative research results justifying the termination of the research Project;

51) **Force majeure** – an event or series of events beyond the control of the parties, which prevent, in whole or in part, the fulfilment of obligations arising from the Co-financing Agreement , which the parties could not have foreseen and which they could not have prevented or overcome even whilst exercising due care;

52) **Standard clinical practice –** means a treatment regimen typically used in the prevention, diagnosis and treatment of diseases and disorders;

53) **Information and Communication Technology system, ICT system** – the system referred to in Article 21(1) of the Act, used to manage the process of accepting Applications for funding and for the submission of documents enabling the monitoring, reporting and verification of the correct implementation of the Agreement (Reports);

54) **Medical technology** – as defined in Article 5(42b) of the Act of 27 August 2004 on healthcare services financed from public funds – comprises medicines, devices, diagnostic and therapeutic procedures used for specific indications, as well as organizational support systems within which healthcare services are provided;

55) **EU –** this should be understood to mean the European Union;

56) **Consortium Agreement –** an agreement concluded between the Consortium Leader and the Consortium Members jointly implementing the Project, which must substantially comply with the template set out in Annex 3 to the Rules and Regulations. The Consortium Agreement must be concluded before the Application is submitted;

57) **Co-financing Agreement (Agreement) –** this should be understood to mean an agreement for the implementation and funding of the Project concluded between the Applicant and the Agency, a template of which is set out in Appendix no. 2a/2b to the Rules and Regulations;

58) **URPL** - the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

59) **Act** – the Act of 21 February 2019 on the Medical Research Agency;

60) **Grant Application (Application) –** an Application for the implementation and funding of the Project, which is submitted as part of the Call for Proposals via the ICT system, the template for which is set out in Appendix no. 1a/1b to the Rules and Regulations;

61) **Applicant -**

a) the entity referred to in Article 17(1)(1, 2, 3, 5)(a) of the Act, which is not a natural person, submitting the Application (in the case of a Single-entity Applicant),

b) The Consortium Leader and the Consortium Members collectively, on behalf of and for the benefit of whom the Consortium Leader submits the

Application (in the case of a Multi-entity Applicant), provided that all entities forming part of the Consortium must have the status of an entity referred to in Article 17(1)(1, 2, 3, 5)(a) of the Act;

62) **Indicator –** a measurable variable required by the Project to monitor the progress of activities;

63) **Device –** Medical device or *in vitro* diagnostic medical device;

The Projects of Clinical Trial for Medical devices or performance study Projects for *in vitro* diagnostic medical devices <u>are not eligible for funding</u> under this Call for Proposals.

64) **Medical device** - within the meaning of Article 2(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC, a medical device is an instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used – either alone or in combination – on human beings for at least one of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, forecasting, treatment or alleviation of a disease,
- diagnosing, monitoring, treating, alleviating or compensating for an injury or disability,
- investigating, replacing or modifying an anatomical structure or a physiological or pathological process or condition,
- providing information through *in vitro* testing of samples taken from the human body, including those taken from organ, blood and tissue donors

and which does not achieve its principal intended effect by pharmacological, immunological or metabolic means in or on the human body, but whose effect may

be enhanced by such means;

65) ***In vitro* diagnostic medical device –** within the meaning of Article 2(2) of Regulation (EU) 2017/746 of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, this is a medical device that is a reagent, reagent product, calibrator, control material, a kit, tool, instrument, equipment, software or system, used alone or in combination, intended by the manufacturer for *in vitro* use for the examination of samples taken from the human body, including blood and tissues taken from donors, solely or principally for the purpose of providing information:

   a) about a physiological or pathological process or condition;

   b) a congenital physical or mental developmental disorder;

   c) a predisposition to a medical condition or illness;

   d) to determine safety and suitability for potential recipients;

   e) to predict responses or reactions to treatment, or

   f) to determine or monitor therapeutic measures;

66) **Project Management** – a set of activities relating to the planning, organization, coordination, monitoring, supervision and accounting for the implementation of a Project, undertaken with the aim of achieving its objectives and outcomes. Project management involves, amongst other things, the planning, implementation and management control of the tasks required to achieve the Project's objectives. Project management primarily involves activities relating to the administrative aspects of the Project – which do not require substantive measures aimed at achieving the Project's objective – as well as systematic cooperation with the Agency regarding reporting and the day-to-day monitoring of the Project;

67) **Application Assessment Panel (AAP)** – a panel appointed by the President to assess Applications submitted as part of the Call for Proposals in accordance with Article 18 of the Act.

2. Overview information about the Call

Call for Proposals ABM/2026/3 is being announced by the Medical Research Agency. The Agency is a state-owned legal entity responsible for the development of scientific research in the fields of medical sciences and health sciences. The Agency's main objective is to support innovation in healthcare, with particular emphasis on the development of, amongst other things, Non-commercial Clinical Trials and Research experiments. MRA is an entity tasked with supporting processes that contribute to increasing innovation within the healthcare system.

The Agency's work in the field of funding scientific Projects will bring tangible benefits to patients and doctors; in particular, it will enable an assessment of which new medical technologies should be adopted to meet the public's healthcare needs and to improve the effectiveness and safety of treatment.

Securing funding for research Projects will also increase the contribution of Polish scientists to the development of medical science.

2.1 Legal basis

These Rules and Regulations have been drawn up pursuant to Article 16(4) of the Act. In accordance with the Act, the Rules and Regulations set out the principles and procedure for selecting Projects recommended for funding. The Rules and Regulations are a guidance document designed to provide potential Applicants with all the information necessary to apply for funding for Projects involving the conduct of Research experiments. This document contains, amongst other things, information on the deadlines, venue and procedure for submitting Applications, a template for the Application and the documents to be attached to it, a template for the agreement on the implementation and co-financing of the Project, detailed criteria for the selection of Projects together with an explanation of their significance, and a template for the Consortium Agreement.

Applicants, when drawing up their Applications and beneficiaries implementing Projects involving Research experiments are required to comply with the rules set out in generally applicable legislation, in particular in the following legal acts:

Statutes:

- the Polish Act of 21 February 2019 on the Medical Research Agency;
- the Polish Act of 5 December 1996 on Professions of Doctor and Dentist;
- the Polish Act of 7 April 2022 on medical devices.

EU Regulations:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC;

Regulations of the Minister of Health:

- Regulation of the Polish Minister of Health of 6 April 2020 on the types, scope and formats of medical records and the method of its processing;
- Regulation of the Polish Minister of Health of 26 January 2023 on the Bioethics Committee and the Bioethics Appeals Committee.

2.2 Justification for the announcement of the Call

The open call for Research experiments (ABM/2026/3) addresses key needs within the healthcare system by directing funding towards Projects that enable the development and evaluation of new medical procedures, including therapeutic, diagnostic or rehabilitative interventions, which clearly contributes to the advancement of medical knowledge.

2.3 Scope of activities covered by the Call

2.3.1 Objective of the Call

The aim of the Call for Proposals is to develop new standards and guidelines for a holistic approach to patient care within the framework of Research experiments that support or accelerate recovery.

The aim of the Call for Proposals is to support Projects that take a holistic approach to patients' health, combining modern treatment methods with the most precise diagnostic techniques. At the same time, the Call for Proposals aims to address an existing research gap and to support interdisciplinary Projects carried out at the intersection of various fields. The integration of different areas will enable: holistic patient care, accurate diagnosis and effective treatment, and will contribute to a lasting improvement in quality of life for patients with various medical conditions.

Particular emphasis was placed on the evaluation of innovative or, to date, insufficiently validated medical procedures, including rehabilitation programmes (also covering psychophysical interventions) and surgical procedures. Funded Projects should enable the determination of the actual clinical value of the interventions under investigation, their impact on treatment outcomes, patients' quality of life, safety of use and the efficient use of healthcare system resources.

The aim of carrying out Research experiments as part of the Call for Proposals is to generate reliable scientific evidence that can form the basis for developing new clinical guidelines or updating existing ones, as well as for the recommendations of scientific societies and decisions concerning the organization and funding of healthcare services. The Call for Proposals therefore supports the implementation of effective, safe and cost-effective medical solutions that address patients' real needs and the challenges facing the modern healthcare system.

Projects submitted as part of the Call for Proposals must have the status of Research experiments.

The following **are not** eligible for funding under this Call:

- Projects involving pre-clinical research;
- Clinical Trial Protocols for Medicinal products;
- Projects involving the administration of a medicinal product on a hospital-only basis;
- Non-interventional studies;
- Observational studies;
- Clinical Trials' Projects involving Medical devices, i.e. Projects aimed at assessing the performance/safety of a device that does not bear the CE marking or of a CE-marked device used outside its intended purpose as specified by the manufacturer;
- Research Projects on the performance of *in vitro* diagnostic medical devices.

Note:

Under the terms of this Call, funding cannot be provided for a Research experiment in which an algorithm, software, tool or device is being tested with the aim of supporting a Medical decision – including a decision by a specialist doctor – which may have consequences for the health or life of a participant in the Research experiment. The development of an algorithm, software, tool or device intended to support a doctor's decision-making should be carried out within the framework of a clinical trial.

In view of the above, the expected outcomes relating to the implementation of *the Open Call for Research Experiments (*ABM/2026/3) have been defined, and these include:

- to identify the most clinically effective medical procedures used for a given condition at the same stage of treatment or diagnosis;
- to provide high-quality scientific evidence to optimize clinical practice guidelines relating to medical procedures and to modify existing standards of medical care;
- improving patients' access to the most clinically effective medical procedures (diagnostic and therapeutic);
- improving patient care by identifying and implementing new or more effective Medical Procedures at a specific stage of the disease's progression;

- standardization of the procedures and documentation required for the registration of Research experiments, as well as improving the quality of monitoring participants' condition during the conduct of these experiments;
- an increase in the number of effective therapeutic (treatment) or diagnostic methods developed as part of Research experiments, which have real potential for implementation within the public healthcare system.

In this Call, where the Applicant plans, as part of the Project, to collect Biological material (peripheral whole blood samples) from study participants for the purpose of carrying out the procedures set out in the Research Experiment Protocol, provided that the research participant gives their informed consent, there is **a requirement to bank the Biological material** for its subsequent use in future scientific or research and development studies **(detailed information in subsection 3.7. *Banking of biological material* (as defined in these Rules and Regulations).**

The Call for Proposals is in line with **the Clinical Research Development Plan for 2020–2030**, under which the Agency's activities are intended to contribute to an increase in the number of Research experiments being conducted.

The outcome of the Project must be the publication of the research results obtained as part of the Project in a peer-reviewed scientific journal, or the acceptance for publication (in print) of a manuscript presenting these results by the journal's editorial board, no later than 6 months from the date of completion of the Project. Publication or acceptance for publication should take place, for example, in one of the scientific journals listed in *the List of Scientific Journals and Peer-Reviewed Materials from International Conferences* in force on the date of publication of the results, as published by the Minister of Science and Higher Education.

2.3.2 Research experiments

The legal basis for assessing whether the submitted Application meets the requirements of the Call for Proposals will be the Act of 5 December 1996 on the professions of doctor and dentist.

The definition of a Research experiment is set out in Article 21(3) of the Act on the Professions of Doctor and Dentist, which states that: *A research experiment aims primarily at expanding medical knowledge. It can be carried out on both a sick and a healthy person. Conducting a research experiment is permissible when participation in it is not associated with risk, or the risk is minimal and is not disproportionate to the possible positive results of such an experiment.*

A Research experiment carried out as part of the Call for Proposals **must include the recruitment of participants for the study**, on whom an intervention will subsequently be carried out or from whom Biological material will be collected for further analysis.

A Research experiment must satisfy all of the following conditions:

- is primarily aimed at advancing medical knowledge;
- participation in it involves no risk, or the risk is minimal and not disproportionate to the potential benefits;
- the outcome of conducting the Research experiment is the verification or development of innovative Medical procedures;
- **the aim of the proposed study is not to evaluate the efficacy of a Medicinal product or a Device**;
- Medicinal products and Devices used as part of a Research experiment must constitute standard clinical practice for the indication under investigation and must be used in accordance with their authorized indication or intended use.

The results of the Research experiment are for non-commercial purposes.

Example 1: [This is a Research experiment]

A study that aims to expand medical knowledge by providing scientific evidence on innovative therapeutic, rehabilitative, diagnostic, preventive or organizational procedures (e.g. a new diagnostic approach, a new therapeutic approach) constitutes a Research experiment.

The aim of a Research experiment may be, for example, to develop innovative treatment and diagnostic procedures, or to verify the most effective treatment regimens.

Example 2: [This is not a Research experiment]

A study that has been designed to assess the performance or efficacy of a Medicinal product or a Medical device does not constitute a Research experiment, but rather a Clinical Trial within the meaning of Regulation 536/2014 and Regulation 2017/745 and is subject to the formal procedures applicable to clinical trials; that is to say, it requires, for example, authorization from the URPL to conduct the Clinical Trial.

Example 3: [This is not a Research experiment]

An investigation in which the intervention being evaluated is the use of the following in participants:

- **a Medicinal product authorized for marketing (low-intervention study);**
- **a Medicinal product not authorized for marketing;**
- **a Medicinal product used for an off-label indication;**
- **a Device without a CE mark;**
- **an uncertified/unavailable-on-the-market algorithm, e.g. one based on machine learning, which meets the definition of a device;**
- **a Device used for an indication other than that for which it is intended, as specified in the conformity assessment;**

is equivalent to an assessment of the performance of the Medicinal product or Device under investigation and, as such, does not constitute a Research experiment but a Clinical Trial.

It is permissible to use, within the Project, Medicinal products authorized for marketing and used in accordance with their registered indications, as well as Devices placed on the market and used in accordance with their intended purpose. At the same time, the aim of the Project must not be to assess the safety, efficacy, performance, effectiveness or other clinical characteristics of these products or Devices. Projects aimed at obtaining evidence

regarding the safety, efficacy or performance of a Medicinal product or a Medical device constitute, respectively, a Clinical Trial of a Medicinal product or a Clinical Trial of a Medical device and are not eligible for funding under the Call for Proposals for Research experiments.

Where the Product is used as part of a Research experiment, the Applicant is required to demonstrate that the Product has been placed on the market and is being used in accordance with its intended purpose.

If, for a Medical device or an *in vitro* diagnostic medical device, documents confirming its compliance with the requirements of Regulation 2017/745 or Regulation 2017/746, as applicable, have been made available in the EUDAMED database, the Applicant is not required to attach an EU declaration of conformity or a certificate of conformity to the Application. In such cases, the Applicant is required to attach a statement containing the product's identification number in the EUDAMED database and information enabling the Agency to verify the documentation.

If the documentation referred to above is not available in the EUDAMED database, the Applicant is required to attach the following to the Application:

- a current EU declaration of conformity for the Device, issued in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council or Regulation (EU) 2017/746 of the European Parliament and of the Council, relating to the Device, or
- a declaration of conformity drawn up in accordance with Council Directive 93/42/EEC, together with a letter from the notified body confirming the submission of a formal Application for a conformity assessment in accordance with the first paragraph of Section 4.3 of Annex VII to Regulation (EU) 2017/745 or the relevant provisions of Regulation (EU) 2017/746 – where applicable to the Device in question.

In particularly justified cases, where it is not possible to attach the documents specified above for reasons beyond the Applicant's control, it is permissible to provide explanations together with other documents confirming that:

- a Medical device or an *in vitro* diagnostic medical device must have an EU declaration of conformity and – where required – a valid certificate of conformity issued by a notified body;
- the Device has been placed on the market;
- the Device is used within the Project in accordance with its intended use and current standard of care;
- the aim of the Project is not to assess the safety, efficacy, performance, effectiveness or any other clinical or diagnostic properties of the Device.

The Beneficiary is required to submit to the Agency the final favourable opinion of the Bioethics Committee on the Research experiment covered by the Project no later than 6 months after the signing of the Co-financing Agreement.

2.3.2.1 Requirements for the Head of Research experiment

In accordance with Article 23(1) and (2) of the Act on the Professions of Doctor and Dentist, **the person in charge of a Research experiment must be a doctor who holds** a specialization in a field of medicine that is particularly relevant to the nature or conduct of the experiment, and who possesses appropriately high professional and research qualifications.

In the case of a Research experiment involving a nonmedical component, the doctor in charge of the experiment shall collaborate with another person possessing the necessary qualifications to carry out the nonmedical component, who shall supervise the conduct of that component.

The person in charge of a Research experiment in Projects funded by the Agency, irrespective of the requirements of the Act of 5 December 1996 on the professions of doctor and dentist, must also hold **at least a doctoral degree in the field of medical and health sciences, including a degree obtained in accordance with previously applicable regulations in the field of medical sciences, or an equivalent degree obtained abroad.**

The requirement that the Head of Research Experiment must hold a doctoral degree in medical or health sciences is mandatory for all Applications concerning Research experiments.

Note:

The same person may not be named as the Head of Research experiment in more than two Applications submitted under this Call for Proposals.

At the same time, it should be borne in mind that the person designated as the Head of Research experiment may not be a member of the bodies of the Medical Research Agency referred to in Article 4 of the Act, as at the date of submission of the Application for funding and throughout the entire duration of the competitive selection procedure until the date of conclusion of the agreement.

2.3.2.2 Principles of Good Clinical Practice

1. Research experiments must comply with the legal provisions set out in the Act on the Professions of Doctor and Dentist and with the principles laid down in the Code of Medical Ethics, namely: Research experiments should be conducted in accordance with ethical principles based on the Declaration of Helsinki and consistent with applicable legislation;
2. A doctor conducting scientific research, and in particular Research experiments, should adhere to the standards and obligations set out in the Code of Medical Ethics and the generally accepted ethical principles governing scientific research;
3. Research experiment may be carried out if the expected therapeutic or cognitive benefit is of significant importance, and the anticipated realization of that benefit, as well as the appropriateness and method of conducting the experiment, are justified in the light of the current state of knowledge and consistent with the ethical principles of the medical profession;

4. It should be borne in mind that the rights, safety and welfare of research participants are of paramount importance and take precedence over the interests of science and society;
5. Research experiments should be scientifically justified and described in a detailed and clear Protocol;
6. Research experiments should be conducted in accordance with the Protocol, which has been previously approved by the Bioethics Committee. Medical care and all medical decisions concerning participants in the Research experiment should always be made by a qualified medical doctor or, where justified, a dentist;
7. The doctor must obtain consent from the person who is to be subjected to the Research experiment, after first informing them of all aspects of the experiment that may affect them and of their right to withdraw from the experiment at any time;
8. A person giving their consent to take part in an experiment must not do so whilst under the influence of a dependence on a doctor or whilst under any form of pressure;
9. Each person conducting the Research experiment should possess the appropriate qualifications: education, training and experience suitable for carrying out the tasks assigned to them in the study;
10. Informed and voluntary consent to participate in the study should be obtained from every person taking part in the Research experiment before they commence the study;
11. A participant who is a minor may take part in the Research experiment provided that all of the following conditions are met:
    1) the expected benefits are of direct relevance to the health of the minor taking part in the Research experiment or of other minors in the same age group;
    2) This Research experiment will significantly advance medical knowledge;
    3) it is not possible to carry out such an experiment with comparable effectiveness involving an adult;
12. All information relating to the Research experiment should be recorded, processed and stored in such a way as to enable it to be properly reported, interpreted and verified;
13. The confidentiality of data enabling the identification of participants in the Research experiment should be protected and upheld in accordance with the applicable

legislation on the protection of personal data, in particular Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 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 – GDPR);

14. Systems and procedures should be put in place to ensure the quality of the research in every respect;
15. The processing of personal data of individuals participating in the Research experiment carried out as part of the Project must also comply with the provisions of the Act of 10 May 2018 on the protection of personal data and other generally applicable legal provisions; and, with regard to biobanking, activities must comply with: the ethical standards set out in the World Medical Association Declaration of Taipei on the ethical considerations regarding health databases and biobanks (2016); the Organization for Economic Co-operation and Development (OECD) Guidelines on Human Biobanks and Genetic Research Databases (2009); the documents governing the conduct of future scientific or research and development studies using human Biological material, as well as the Quality Standards for Polish Biobanks v. 2.00 (2021) and their updates, or in accordance with the ISO 20387-2018 or ISO 20387-2021 standard, as confirmed by a certificate.

2.4 Amount of funding allocated to the Call

The amount of funding allocated for the co-financing of Projects selected under the Call is **PLN 125,000,000 (in words: one hundred and twenty-five million Polish zlotys)**. In accordance with Article 19(7) of the Act, the President may increase the amount of funding allocated to the Call for Proposals. Information regarding any increase in the allocation will be published on the website www.abm.gov.pl.

The maximum permissible level of funding for the Project is 100 per cent of the Project costs, provided that **the total cost of the Project does not exceed PLN 12,000,000 (in words: twelve million Polish zlotys).**

There is no lower limit on the total cost of a Project in this Call for Proposals.

Under the terms of the Call for Proposals, it is not possible to provide public aid through MRA.

If the Applicant carries out both commercial and non-commercial activities, the Application may relate only to a Project carried out within the non-commercial part of their activities. The level of funding for the non-economic component is up to 100 per cent of eligible costs. Where the Applicant carries out both commercial and non-commercial activities, they are required to ensure that the financing of these categories of activity is kept separate; in particular, the two types of activity, as well as their costs, financing and revenue, must be kept separate in order to avoid cross-subsidisation of the commercial activities. The accounting separation of a specific business activity involves keeping separate records for that business activity and correctly allocating income and costs on the basis of consistently applied and objectively justified methods, as well as setting out in the documentation, referred to in Article 10 of the Accounting Act, the principles for maintaining separate records and the methods for allocating costs and revenue.

2.5 Entities eligible to submit Applications

The entities specified in Article 17(1)(1–3 and 5)(a) of the Act can participate in this Call for Proposals:

- the entities referred to in Article 7(1)(1–6 and 8) of the Polish Act of 20th July 2018 on higher education and science, i.e.:
  - higher education institutions;
  - federations of entities of the higher education system and science;
  - the Polish Academy of Sciences acting on the basis of the Polish Act of 30th April 2010 on the Polish Academy of Sciences, hereinafter referred to as "PAN";
  - scientific institutes of the PAN operating under the Act on the PAN;
  - research institutes, operating under the Polish Act of 30th April 2010 on

research institutes;

- international scientific institutes established on the basis of separate acts and operating on the territory of the Republic of Poland;
- other entities conducting predominantly scientific activities on an independent and continuous basis;

- conducting scientific research and development work:
  a) organizational units with legal personality and registered office within the territory of the Republic of Poland.

Entities referred to in Article 17(1)(4) and (5)(b) of the Act <u>are excluded</u> from participation in this Call for Proposals, namely:

- **entrepreneurs with the status of a research and development centre within the meaning of Article 17(2) of the Act of 30 May 2008 on certain forms of support for innovative activities;**
- **entrepreneurs carrying out scientific research and development work who operate in an organizational form other than that specified in Article 17(1)(3) and (4) of the Act.**

The purpose of the Beneficiary's activities in carrying out a Research experiment must not be to make a profit from the conduct and organization of Clinical Trials or Research experiments.

Applicants are required to submit a declaration stating that they have not received or applied for funding for the activities covered by the Application from public funds originating from other sources (e.g. the National Centre for Research and Development, the National Science Centre, the National Health Fund).

The terms 'financing' and 'applying for funding' for the tasks covered by the Application from public funds from other sources shall also be understood to include a situation where **the Application <u>is currently being considered</u>** under:

- application procedures for other calls for proposals or programmes funded wholly or partly from public funds;
- procedures for lodging protests;
- any other appeal or court proceedings.

Note:

A single organization may submit a maximum **of four Applications in the role of Single-entity Applicant, Consortium Leader or Consortium Member.**

Where a Single-entity Applicant, a Consortium Leader or a Consortium Member has branches which are entered in the National Court Register under the same KRS number, these branches **are deemed to be the same Single-entity Applicant/Consortium Leader/Consortium Member**.

Entities subject to registration in the National Court Register which are participating in the Call for Proposals must have been registered in the National Court Register for at least three years prior to submitting an Application for funding under this Call for Proposals.

Furthermore, as at the date of submission of the Grant Application, Single-entity Applicants, the Consortium Leader and Consortium Members carrying out economic activities within the meaning of EU competition law are required to maintain separate economic and non-economic activities.

2.5.1 Consortium

Applications may be submitted by a consortium formed for the purpose of carrying out the Project. Given that the Project may be carried out at multiple sites, MRA requires that the number of entities forming the Consortium be limited to **a maximum of four,** with any other sites collaborating with the Consortium as subcontractors.

Note:

An entity that participates **only in** the clinical part specified in the research Protocol (a site) **cannot be regarded as a Consortium Member, but only as a subcontractor**. However, an

entity that is involved at every stage of the Project (i.e. participates in drawing up the Project's objectives, drafting the research Protocol, recruiting participants for the Research experiment, carrying out the procedures set out in the Protocol, and analysing the data obtained during the research) may be regarded as a Consortium Member. **The Consortium Member is jointly and severally liable** for the implementation of the Project, together with the Consortium Leader and the other Consortium Members.

Each of the entities listed as members of the Consortium should have a team, the necessary infrastructure and experience in activities aimed at treating patients or improving their health. The Consortium Leader and the Consortium Members jointly implement the Project in terms of both content and finance, i.e. they jointly participate in:

- in the development of the research Project, including, in particular, their participation in the preparation of the proposal's objectives and the design of the Protocol;
- during the study registration process;
- in the analysis of data resulting from the Research experiment;
- in bearing the costs associated with the implementation of the Project.

Furthermore, they are mutually obliged to work together towards achieving the Project's objective and **are jointly and severally liable to the Agency for the proper implementation of the co-funded Project**. In this regard, they are obliged to act in a coordinated manner. The tasks carried out under the Project must be in accordance with the Consortium Agreement, and no other civil law contracts relating to the implementation of this Project may be entered into between the members of the Consortium.

2.5.2 Principles of formulating the Consortium

The Consortium Agreement must be concluded before the Grant Application is submitted and must be attached to the Grant Application.

In cases justified by the need to ensure the proper and timely implementation of the Project, a Consortium Member may be replaced, with MRA's consent, following the signing

of the Co-financing Agreement. Such a change shall be permitted no earlier than after a duly executed security for the proper performance of the Co-financing Agreement has been provided (if required) and the first tranche of funding has been disbursed, and shall require an annex to the Co-financing Agreement in order to be valid.

Note:

An entity that has been excluded from receiving funding may not be a member of the Consortium.

The Consortium Parties shall enter into a Consortium Agreement with one another in accordance with the procedure referred to above and affix qualified electronic signatures thereto (compliant with the eIDAS Regulation (EU) No 910/2014; using a graphical symbol). The Consortium Agreement must be drawn up in Polish. The Consortium Agreement should be **signed with a qualified electronic signature by the Consortium Leader and all Consortium Members**. The Consortium Agreement concluded by the parties in ordinary written form must be certified electronically (using a qualified electronic signature in accordance with the eIDAS Regulation (EU) No 910/2014; using a graphic symbol) as a true copy of the original by a notary in accordance with Article 97(2) of the Act of 14 February 1991 – the Notaries. The Consortium Agreement template sets out the minimum scope of provisions that should be included in the Consortium Agreement (Appendix 3 to the Rules and Regulations). The parties to the Consortium Agreement may set out specific provisions in its text, including their mutual rights and obligations and claims for recourse, provided that such provisions do not contravene the provisions of the Rules and Regulations and their appendixes, including the Co-financing Agreement. The scope of the Consortium Agreement may be extended in accordance with the needs of the Consortium Members.

If an additional entity joins the Consortium during the implementation phase of the Co-financing Agreement, as a general rule, the total budget of the Project shall not be increased; however, funds may be reallocated between tasks and Consortium Members in accordance with the terms set out in the Co-financing Agreement.

2.5.3 Subcontracting

Subcontracting within the framework of the Project means entrusting a natural person, a legal person or an organizational unit without legal personality, on the basis of contracts, with the performance of activities within the framework of a given Project; for example, entrusting external entities with the recruitment of participants for the Research experiment and the conduct of diagnostic tests as provided for in the Protocol.

Expenditure incurred by the Subcontractor in carrying out the tasks may constitute eligible expenditure, provided that it is specified in the approved Application. The actual performance of the subject matter of the contract concluded with the Subcontractor must be documented in accordance with the contract concluded with the Subcontractor, e.g. by means of a written report on the acceptance of the task, acceptance of the work carried out, etc.

Under the Project, the Consortium Leader and the Consortium Members shall not enter into civil law agreements, including, in particular, those relating to the commissioning of technical services or services for the implementation of the clinical part, between Consortium Members (this also applies to the Consortium Leader). The tasks carried out under the Project must be in accordance with the Consortium Agreement, and no other civil-law contracts relating to this Project may be entered into between the members of the Consortium.

Where a contract is concluded with a subcontractor in connection with the Project, the single-entity Beneficiary/Consortium Leader undertakes to provide all documents necessary to verify the eligibility of expenditure.

In justified cases and with the Agency's consent, the Applicant may, during the implementation of the Project, use the services of a subcontractor or subcontractors with registered office outside the Republic of Poland. A subcontractor may not act as the Applicant or Beneficiary in the Project.

2.5.4 Procedure for selection of the Subcontractor for the clinical part of the Research experiment

The selection of a subcontractor to carry out the clinical part of the Project may, in justified circumstances, be exempt from the Application of the Act of 11 September 2019. The Public Procurement Act, hereinafter referred to as the 'PPA', provided that the conditions set out in Article 11(1)(3) of the aforementioned PPA, concerning contracts for research or development services, are met.

It should be noted, however, that the Beneficiary is responsible for conducting the procedure in accordance with the Public Procurement Act, whilst ensuring that evidence can be provided to demonstrate that a lawful procedure has been followed, or that a justification is provided where an exemption from public procurement procedures is applied.

The Beneficiary remains obliged to incur expenditure in accordance with the principles of reasonableness, fair competition, openness and transparency, and without any conflict of interest arising from the performance of the Co-financing Agreement.

The selection of a subcontractor for the Project should be carried out in accordance with the rules set out in subsection 3.4 of the Rules and Regulations.

The use of the names of subcontractors for services or supplies (or the names of goods/products) in the Application does not exempt the Applicant from the obligation to carry out the appropriate procedure for selecting a subcontractor (including the need to consider equivalent solutions), in accordance with the applicable regulations and the provisions of the Rules and Regulations.

2.6 Procedure for submitting Applications

Applications must be submitted electronically via the MRA ICT System, available at the following web address https://konkurs.abm.gov.pl.

The Application, together with its appendixes, must be submitted/completed in Polish or English (except for fields where a specific language is specified).

Formal attachments must be prepared in Polish.

When completing the Application, please ensure that it contains information directly relating to the assessment criteria described in subsection 4.1.1. The Formal Assessment Criteria and in Appendixes 6 (Template for the Substantive Evaluation Form) and 7 (Template for the Panel Evaluation Form) to the Rules and Regulations, **as the assessment of these criteria is based solely on the information contained in the Application.**

In the event of technical problems relating to the operation of the ICT system, the President may authorize the submission of Applications in a format other than via the ICT system. Information regarding the change to the procedure for submitting Applications will be posted on the Agency's website.

2.7 Deadlines

The Applications must be submitted from 15 September 2026 at 12:00:00 until 17 November 2026 at 12:00:59 (Central European Time), exclusively in electronic form via the MRA ICT System available at the following web address: https://konkurs.abm.gov.pl, unless information regarding a change to the method of submitting Applications has been published on the Agency's website.

Implementation of the Project must commence no earlier than 1 September 2027 and no later than 2 November 2027.

The minimum planned duration of the Project at the time of submitting the Application is 3 years (36 months). The maximum planned duration of the Project at the time of submitting the Application is 5 years (60 months).

The date on which the Application is submitted via the IT system shall be deemed to be the date of receipt of the Application.

3. Principles of financing Research experiments by the Medical Research Agency

In accordance with the terms of the Call for Proposals, funding may cover up to 100 per cent of the costs associated with the Project.

Project costs will be settled on the basis of **expenditure actually incurred – direct costs and indirect costs.**

3.1 Tasks planned under the Project

The Agency requires that, as part of the work schedule set out in the Application, the planned Project tasks and the method of their implementation be set out. Each task should include appropriate Milestones, enabling an objective assessment of progress in the implementation of the Project. A Milestone refers to a significant point or achievement within the Project that has a major impact on its progress. Examples of Milestones: Preparation of the Research experiment Protocol (drafting of the Research experiment documentation); Obtaining *approvals*– receiving a favourable opinion from the Bioethics Committee regarding the Research experiment. A Milestone is not the completion of the contractor selection procedure, Project management. MRA recommends that the completion date for Milestones be specified by indicating the exact day on which they are to be achieved.

As part of the work schedule set out in the Application, a maximum of 6 tasks may be planned; however, the Application must specify 2 mandatory tasks, namely *'Research Management'* and *'Conduct of the Clinical Part'*. Mandatory tasks have strictly defined Milestones (section 3.1.1.2.). For each task outside the compulsory pool, you must identify between one and two Milestones.

1. *Research management* – a task, under which the costs of the salaries of staff directly involved in carrying out the Research experiment must be taken into account, including costs associated with the substantive management of the Project, including those incurred by the Head of Research Experiment. As part of the implementation of the Project, it is possible to appoint a Project Manager (accounted for under direct/actual costs) who will be responsible, amongst other things, for coordinating the entire

Project in terms of content. The Project Manager may be employed by the Single-entity Applicant or the Consortium Leader. The table below sets out an example of the distinction between the role of a Project Manager and that of Administrative Manager.

	Direct costs	**Indirect costs**
Area	**Project Manager**	**Administrative Manager**
Research strategy and planning	He is responsible for the strategic and substantive supervision of the Research experiment; he sets the research objectives, draws up the research Protocol and oversees its implementation from a scientific perspective.	Responsible for carrying out Project tasks in accordance with the work schedule and based on the metrics set by the Project Manager.
Team management	He supervises the research team from a scientific perspective, provides expert support and monitors progress towards the research objectives.	Coordinates day-to-day operational tasks and administrative matters relating to the implementation of the Project.
Relations with partners	He works with key subject-matter partners, such as academic institutions, regulatory authorities and ethics committees.	He maintains regular, operational contact with the funding body and the Consortium Members.
Monitoring the progress of the research	Oversees the progress of the research in the context of achieving the research objectives, prepares reports on the research findings and compiles publications.	Oversees the implementation of tasks at an operational level, ensuring compliance with the work schedule and the effective management of financial and technical resources.

Project budget	He is responsible for allocating resources in line with the research objectives and works with the administrative manager on key decisions.	He is responsible for managing the Project's budget.
Documentation	Oversees the preparation of substantive documentation, including the research Protocol and procedures relating to substantive areas, particularly with regard to the assessment of research safety.	He ensures that tasks relating to the preparation of documentation for the Research experiment are carried out on time and also oversees the process of preparing all applications for authorizations and permits.
Risk management	It is responsible for managing key risks, particularly in relation to the achievement of scientific objectives, the justification for the study and decision-making regarding amendments to the research protocol.	He analyses operational risks associated with the performance of tasks on an ongoing basis and refers key issues to the line manager for resolution.
Project Completion	He finally approves the Final Report and the Research Experiment Report.	Coordinates the administrative formalities relating to the completion of the Project.

As part of this task, the completion dates for the mandatory Milestones must be taken into account (for further information, see section 3.1.1.2)**:**

- Preparation of a Research experiment Protocol (compilation of Research experiment documentation);
- *O*btaining approvals - receiving a favourable opinion from the Bioethics Committee regarding the Research experiment.

The Beneficiary undertakes to carry out an external audit in accordance with the 'Guidelines for Auditors of Projects Funded by the Medical Research Agency', which form Appendix 11 to the Call for Proposal Rules and Regulations.

The requirement to carry out an audit applies only to Projects for which the amount of funding specified in the Application is equal to or exceeds PLN 3 million (in words: three million zlotys).

2. *Implementation of the clinical part* – a task, which must take into account the costs of recruiting, treating and monitoring participants in the Research experiment.

   As part of this task, the completion dates for the mandatory Milestones must be taken into account (for further information, see section 3.1.1.2)**:**

   For single-site and multi-site Projects:

   - First Site Activation (FSA);

   For multi-site Projects (in the case of single-site Projects, these Milestones will remain inactive)[1]**:**

   - Activation of 50 per cent of sites;
   - Activation of the last site; 100% of sites activated (Last Site Activated, LSA).

   For Projects in which the randomization of participants in a Research experiment is planned, the mandatory Milestones are[2]**:**

   - Enrolment of the first randomized participant in the Research Experiment (First Patient Randomized, FPR);
   - Enrolment of 25 per cent of the randomized participants in the Research experiment;
   - Enrolment of 50 per cent of the randomized participants in the Research experiment;

[1]The specified Milestones are mandatory only if, in the Indicator: A numerical value greater than 1 is entered in the 'Number of sites conducting the Research Experiment under the Project' field.
[2]The Milestones listed are mandatory only if the Applicant ticks the relevant box in the Application form: S – study design (type of proposed study) Does the project involve randomization of participants? 'YES'

- Enrolment of 75 per cent of the randomized participants in the Research experiment;
- Enrolment of the last randomized participant in the Research experiment; 100 per cent of participants in the Research experiment have been enrolled (Last Patient Randomized, LPR).

For Projects in which there are no plans to randomize participants in the Research experiment, the mandatory Milestones are[3]:

- Enrolment of the first participant in the Research experiment;
- Enrolment of 25 per cent of the participants in the Research experiment;
- Enrolment of 50 per cent of the participants in the Research experiment;
- Enrolment of 75 per cent of the participants in the Research experiment;
- The final participant in the Research experiment has been enrolled; 100 per cent of the participants in the Research experiment have now been enrolled.

For all Projects the following Milestones are also mandatory:

- Closure of databases; completion of the process of entering, verifying and approving data;
- To carry out the final analysis and submit the final report on the Research experiment to the Medical Research Agency.

Within the approved cost estimate for the entire Project, **a maximum of 100 budget items** may be planned.

As part of the Project, it is possible to use the Electronic Case Report Form (eCRF) made available by the Agency. The use of the aforementioned eCRF will require the submission of the 'eCRF MRA Data Form' and the signing of the Entrustment Agreement, both of which form appendixes to the Co-financing Agreement. Information on the eCRF provided by MRA can be found at https://abm.gov.pl/pl/dla-beneficjenta/ecrf-abm/informacje-podstawowe/2551,Informacje-podstawowe.html.

[3]This Milestone is mandatory only if the Applicant ticks the relevant box on the Application form: S – study design (type of proposed study) Does the project involve randomization of participants? 'NO'

3.1.1 Methodology for Indicators and Milestones

The Methodology of Indicators and Milestones provides a systematic approach to planning, monitoring and reporting on progress in the implementation of the Project. Its primary function is to ensure transparency in assessing the extent to which individual tasks have been completed and to enable the ongoing and final verification of the results of Projects funded under the Call for Proposals.

Indicators and Milestones serve complementary functions:

— Indicators are quantitative in nature and are used to systematically monitor progress in the implementation of measures;

— Milestones are key points in the schedule that confirm the completion of a specific stage of the Project.

Achieving the target values for the indicators and meeting the Milestones form the basis for assessing the Project's progress.

3.1.1.1 Indicators

The table below sets out the criteria applicable to the Call for Proposals:

Name of the Indicator	**Methodology of the Indicator**
Output indicators	
Number of validated innovative therapeutic developed within Research experiment	This indicator covers the number of therapeutic or diagnostic methods for which the Beneficiary will present clinical data in the Final Report demonstrating the potential for the method to be used within the healthcare system in Poland.
Number of participants included in Research experiment	This indicator specifies the number of participants in the Research experiment who have given their

	informed written consent to take part in the Research experiment.
The number of Research experiments initiated in Poland in line with regulatory requirements	This indicator refers to the number of Research experiments carried out as part of the Project which were initiated in accordance with national regulatory requirements, i.e. after receiving a favourable opinion from the Bioethics Committee. Each Project comprises one Research experiment; therefore, the value of the indicator is always '1'.
Number of sites involved in the implementation of Research experiments under the Project	This indicator reflects the number of separate sites where the Research experiment is being carried out as part of the Project. A healthcare facility is defined as a healthcare organization which: • was listed as a site participating in the Research experiment, • an agreement was signed with that entity regarding participation in a Research experiment, and • at least one participant from this site has been enrolled in the Research experiment (which is equivalent to that participant signing the informed consent form to take part in the Research experiment).

Number of biobanked biological material samples for the purposes of the Medical Research Agency (MRA)	An integer (greater than 0) must be entered if the Applicant has planned to collect Biological material solely on the basis of the Agreement on the collection, storage, preservation, transfer and provision of Material, including Biological material, for the purposes of future scientific or research – development, which forms Appendix 4 to the Rules and Regulations. The data provided in the Indicator should be consistent with the description set out in Application II. B in the field 'Applicant's Declaration (that, in the case of biobanking, this will take place at a biobank operating in accordance with the Quality Standards for Polish Biobanks v. 2.00 (2021) and their updates, or in accordance with ISO 20387-2018 or a later version of that standard, as confirmed by a certificate)', where the Applicant should describe the assumptions on the basis of which they estimated the number of Biological material samples (the reasons and estimates for the assumption that Biological material samples will be collected from, for example, 50 per cent of patients or 25 per cent of patients should be specified). By way of exception, it is permissible to enter 'zero' for this indicator where the Applicant does not intend to collect any Biological material, as specified in the Project's terms, or where none of the participants has given their informed and voluntary consent to do so.

	Note: Under this Indicator, it is not permitted to include samples of biobanked Biological material other than those collected pursuant to the Agreement constituting Appendix 4 to the Rules and Regulations.
Output indicators	
Number of publications with the results of Research experiment	This indicator measures the number of publications that: • were based on the results obtained from the ongoing Project, • clearly identify the procedures set out in the Research Experiment Protocol and the Grant Application, • have been published in a national or international scientific journal with details of the Project number and MRA identified as the funding body. At least one of the authors must be a member of the research team and have their affiliation with the organization implementing the Project specified.

3.1.1.2 Milestones

Task 1: Research management

Name of Milestone	The Milestone Methodology

Preparation of the Research experiment protocol (Development of the Research experiment documentation);	Reaching this Milestone marks the completion of work on the full documentation for the Research experiment, in particular: • finalizing the final version **of the Research Protocol (**setting out the objectives, population, interventions, schedule of procedures, and statistical analysis plan), • drafting templates for **participants' informed consent forms**.
Obtaining consents and approvals – obtaining a positive opinion from the Bioethics Committee regarding the Research experiment	Reaching this Milestone means obtaining a favourable opinion from the Bioethics Committee regarding the Research experiment, as confirmed by the receipt of the relevant document. Recommendation: Where a favourable opinion from the Bioethics Committee has been obtained prior to the submission of the Grant Application, the date on which the Project commences should be specified as the date on which the Milestone is achieved.

Task 2: Conducting the clinical part

Name of Milestone	The Milestone Methodology
First Site Activation (FSA)	Reaching this Milestone signifies the approval of the first site's readiness to conduct the Research experiment, i.e. the formal completion of preparations for the start of participant recruitment for the Research experiment. It is required to enter into a

	collaboration agreement with the site, to train the entire research team in good clinical practice and the Experimental Protocol, and to carry out and approve the initiation visit. The Milestone is deemed to have been reached on the date of formal approval of the site's readiness to conduct the Research experiment.
Activation of 50% of sites	A Milestone is defined as the activation of at least 50%of all planned research sites envisaged in the Project. This number is calculated as a percentage and rounded up to the nearest integer. A Milestone is only considered to have been reached once the required number of sites has been activated. Example: If the Project plans for 9 research sites, 50% is 4.5, therefore, the Milestone is reached once at least 5 sites have been activated.
Activation of the last site; 100% of sites activated (Last Site Activated, LSA)	This Milestone marks the activation of all the research sites planned under the Project. A Milestone is considered to have been reached once 100 per cent of the planned sites have been activated. Example: For the 9 planned sites: all 9 sites must be activated.
First Patient Randomized (FPR)	The inclusion of a randomized participant in the Research experiment is defined as the participant signing an informed consent form to take part in the Research experiment, participating in the screening

	procedure, and receiving a positive recommendation for assignment to the Research Experiment arm.
Inclusion of 25% randomized participants	This involves including 25% of the randomized participants in the Research experiment. The number of participants is calculated as a percentage and rounded up to the nearest whole number.
Inclusion of 50% randomized participants	This involves the inclusion of 50% of the randomized participants in the Research experiment. The number of participants is calculated as a percentage and rounded up to the nearest integer.
Inclusion of 75% randomized participants	This involves the inclusion of 75% of the randomized participants in the Research experiment. The number of participants is calculated as a percentage and rounded up to the nearest integer.
Last Patient Randomized (LPR); 100% of randomized participants included	This involves the inclusion of 100% of the randomized participants in the Research experiment.
Inclusion of the first participant	The inclusion of a participant in a Research experiment shall be understood as **meeting the following conditions jointly**: 1. the participant's signing of an informed consent form to take part in the Research experiment, and 2. confirmation that the participant is eligible to take part, in accordance with the Research Experiment Protocol.

Inclusion of 25% participants	This involves the inclusion of 25% of the participants in the Research experiment. The number of participants is calculated as a percentage and rounded up to the nearest integer.
Inclusion of 50% participants	This involves the inclusion of 50% of the participants in the Research experiment. The number of participants is calculated as a percentage and rounded up to the nearest whole number.
Inclusion of 75% participants	This involves the inclusion of 75% of the Research experiment participants. The number of participants is calculated as a percentage and rounded up to the nearest integer.
Inclusion of the last participant in the Research experiment; 100% of participants included	This involves the inclusion of 100% of the Research experiment participants.
Database lock; completion of data entry, verification, and approval processes	Database lock marks the end of the process of collecting and verifying data from the Research experiment. A Milestone is considered to have been achieved when all participants' data has been collected and documented, and the Beneficiary has locked the database. Once the database is locked, the data can no longer be edited and is ready for statistical analysis.
Final analysis and submission of the final report on the Research experiment to the Medical Research Agency	This Milestone marks the completion of data analysis from the Research experiment in accordance with the approved statistical analysis plan. Confirmation that a Milestone has been achieved is the submission of the

	Experiment Report to the Medical Research Agency as an annex to the Final Progress Report. Note: The Milestone must be completed by the final day of the Project at the latest.

3.2. Catalogue of eligible costs

The catalogue of eligible costs set out in this subsection and in Appendix 5 to the Rules and Regulations of the Call for Proposals – *Catalogue of Most Common Costs* – is not an exhaustive list; it is provided for information purposes only, and the data contained therein is intended to facilitate the planning and allocation of costs within the proposed Project.

When planning expenditure in the budget, the Applicant must, first and foremost:

- comply with the rule prohibiting double funding of expenditure from public sources;
- plan expenditure in accordance with the principle of reasonable and efficient use of funds;
- check whether VAT is eligible for recovery (i.e. whether it can be reclaimed by any entity carrying out tasks under the Project);
- set out the method of cost calculation that supports the market price. The Applicant may adopt values higher than those indicated in the Catalogue of Most Common Costs only if they provide a justification setting out the basis for their calculation and confirming the validity and reasonableness of the valuation adopted.

Example 1:

Under the *'Research Management'* task in the 'Remuneration' category, the Applicant has budgeted an expenditure of PLN 1,296,000.00.

Description of the cost calculation method:

Plans are in place to recruit six people:

Head of Research Experiment: 1 person, employment contract, 1 FTE, 40 months, gross salary including employer costs: PLN 10,000.00 (1 person * 40 * 10,000.00 = 400,000.00)

Project Manager: 1 person, contract for specific work, 40 months, gross remuneration including the client's costs: PLN 8,000.00 (1 person * 40 * 8,000.00 = 320,000.00)

Research staff: 4 people, salary supplement, 36 months, gross salary including employer costs: PLN 4,000.00 (4 people * 36 * 4,000.00 = 576,000.00)

Example 2:

Under the task *'Implementation of the clinical part'* in the 'Medical service' category, the Applicant has budgeted an expenditure of PLN 16,400.00.

Description of the cost calculation method:

To carry out preliminary studies involving 100 Research experiment participants comprising:

1. Full blood count – PLN 7.00
2. Urinalysis – PLN 7.00
3. Abdominal and pelvic ultrasound scan – PLN 150.00

PLN 164.00 * 100 = PLN 16,400.00

An expenditure may be considered **eligible if it meets all of the following conditions**:

- is essential for the achievement of the Project's objectives and indicators and was incurred in connection with the implementation of the Project;
- is in accordance with the provisions of the Co-financing Agreement;
- was specified in the approved Co-financing Agreement;
- is recorded and documented in accordance with the applicable regulations, including, in particular, the Accounting Act of 29 September 1994, including the accounting policy applied by the Beneficiary and the terms of the Co-financing Agreement;

- was actually incurred on a cash basis during the Project implementation period specified in the Co-financing Agreement, excluding indirect costs and depreciation, as well as settlements made on the basis of an accounting note and setoffs arising when two parties are simultaneously debtors and creditors to one another;
- was incurred in a reasonable and effective manner, in accordance with the principles of achieving the best results from the given expenditure;
- complies with the applicable legal provisions, in particular with Public Procurement Act, where applicable.

All eligible expenditure must be incurred in accordance with the principles of fair competition, openness and transparency, and without any conflict of interest, which is understood to mean circumstances that could lead to a loss of impartiality or objectivity in connection with the implementation of the Co-financing Agreement.

The inclusion of a particular item of expenditure in the Grant Application does not automatically mean that it is considered an eligible expenditure.

VAT eligibility

Value Added Tax (VAT) charged may be an eligible expenditure under the Project, either in part or in full, if, in accordance with separate regulations, the Single-entity Applicant, the Consortium Leader or the Consortium Members are not entitled to a refund or deduction of this tax, and if this tax was charged in connection with the eligible expenditure incurred.

The Applicant is required to submit *a VAT eligibility declaration* by selecting the appropriate status regarding the legal possibility of reclaiming VAT in the Grant Application. Where an Application is submitted by a Consortium, **each member of the Consortium must submit a separate Declaration as part of the Grant Application. The Beneficiary shall inform MRA of any change in its ability to deduct input VAT from output VAT in connection with expenditure incurred under the Project.**

3.2.1 Remuneration

Under the Project, costs relating to the employment of research staff may be incurred

(including, for example: Head of Research Experiment, Project Manager, data manager, research staff and technical staff).

Costs relating to the management of the research, including the costs of the administrative manager and administrative staff, may not be charged to the 'Remuneration' category.

It should be noted that the person acting as the Head of Research experiment may not simultaneously hold the post of Project Manager. The remuneration for the Project Manager may be similar to that of the Head of Research experiment but must not exceed it.

Staff remuneration costs may be eligible under the Project, provided they are justified and arise from the specific nature of the Project. The manner and scope of staff involvement must be determined by the substantive scope of the Project and must be specified in the Application.

Project staff comprise individuals engaged to carry out tasks or activities within the framework of the Project on the basis of:

- employment relationship (full-time or part-time);
- civil law contracts (including contractual agreements);
- remuneration supplement.

Expenditure relating to staff remuneration must be incurred in accordance with national legislation, in particular the Act of 26 June 1974 – the Labour Code.

Where a civil law contract is concluded with one's own employee, the scope of the tasks/duties set out in that contract and the deadline for their completion must be clearly distinct in nature from the tasks/duties and the deadline for their completion as specified in the employment contract, in the applicable legislation or in internal regulations. Remuneration and other costs associated with the performance of activities under a civil-law contract shall not be recognized as eligible expenditure if, by virtue of their nature, scope, manner of performance or organizational subordination, such activities should be carried out within the framework of an existing employment relationship. Costs relating to tasks that are identical or similar to an employee's duties are deemed ineligible, even if

they are covered by a separate contract under civil law or are carried out outside standard working hours. At the Agency's request, the Beneficiary is required to demonstrate that the activities carried out under a civil-law contract are independent in nature, distinct from the duties of an employee, do not fall within the scope of the duties of the post, and could not, in accordance with the law and the actual nature of the employment, be entrusted to an employee under an employment contract. If it is found that such a distinction does not exist, expenditure relating to the performance of a civil law contract will be deemed ineligible in its entirety.

Example: The duties of a research team member, as set out in the employment contract concluded with the Beneficiary, include, for example, participation in the Research experiments being carried out. The Beneficiary has also entered into a civil-law contract with that person for them to act as an investigator on the funded Project. Expenditure incurred under such a civil law contract cannot be regarded as eligible under the Project.

The remuneration rates under the Project should correspond to the rates actually applied within the entity to the same or comparable positions, or to positions requiring comparable qualifications. If there is no equivalent post within the organization in question, reference should be made to market rates.

Eligible components of staff remuneration are the costs incurred by the employer, in accordance with the relevant provisions of national law and as set out in the institution's remuneration rules and regulations, which must have been in force for at least six months prior to the submission of the Grant Application and must cover all employees of the institution, and the rules for awarding such remuneration are the same for staff involved in the implementation of Projects and for the Beneficiary's other employees, in particular:

- basic remuneration;
- employer's social security contributions;
- contributions to the Labour Fund, the Guaranteed Employee Benefits Fund, allocations to the Company Social Benefits Fund, Employee Capital Plans and the

Employee Pension Scheme;

- an additional annual remuneration proportional to the level of involvement in the Project;
- remuneration for remote work, proportionate to the level of involvement in the Project;
- contributions and optional charges, if these have been included in the calculation of remuneration in the Application.

In the event of a temporary increase in a person's work responsibilities, remuneration supplements and bonuses may also be considered eligible costs relating to remuneration.

An allowance may be considered an eligible cost, provided that all of the following conditions are met:

a) the allowance is provided for in the institution's work regulations or remuneration regulations, or in other applicable provisions of labour law;
b) the regulations referred to in point (a) have been in force at the institution for at least 6 months prior to the submission of the Grant Application;
c) the allowance is potentially available to all employees of the institution concerned, and the rules governing its award are the same for personnel engaged in the implementation of Projects and for the Beneficiary's other employees;
d) the allowance is eligible only for the period during which the person concerned is involved in the Project;
e) the amount of the allowance depends on the scope of the additional duties.

Remuneration supplements are eligible up to 50 per cent of the basic monthly remuneration applicable to the employee in question in the month in which the salary is paid[4], provided that any excess over this limit may result solely from generally applicable legislation (e.g. in accordance with Article 138(3) of the Act on Higher Education and

[4]The basic monthly remuneration is defined as the remuneration which, in accordance with the rules adopted by the employer in question, forms the basis for the award of an allowance. Allowances paid under a single Project must not, in total, exceed the specified basic salary limit, regardless of the number of tasks for which they are paid.

Science).

Bonuses may be considered eligible costs under the Project, provided that the employee in question is involved in the implementation of the Project under an employment contract for at least half-time position. The bonus should be paid in proportion to the individual's level of involvement in the Project; that is, if the individual is working on the Project on a half-time basis, 50 per cent of the bonus paid is eligible. If, under the Project, a particular employee does not receive a funded basic salary, their bonus cannot constitute an eligible cost.

Responsibility for selecting the forms of staff involvement in the Project, and for ensuring that these comply with the Act of 26 June 1974 – the Labour Code, the organization's internal regulations and these Rules and Regulations, rests with the Beneficiary.

3.2.1.1 Head of Research experiment

The Project should name a single Head of Research experiment who:

- meets the regulatory definition of a Head of Research experiment;
- was specified in the relevant field on the Grant Application;
- is the originator and co-creator of the Project's design principles.

The remuneration of this Head of Research experiment should be calculated at a level commensurate with the scope of their responsibilities and involvement in the implementation of the Project, taking into account the recommendations set out in Appendix 5 to the Call for Proposals' Rules and Regulations – *Catalogue of most common costs*.

The Call for Proposals' rules and regulations allow for the possibility of naming more than one Heads of Research experiment in the Project (a maximum of one per site carrying out the Project). In the case of individuals acting as Heads of Research Experiment at individual sites implementing the Project, who have not been designated as the principal Head of Research Experiment, remuneration costs should be budgeted in accordance with the recommendations set out for the post of 'physician-investigator'. The mere fact of holding

the post of Head of Research experiment at a given site does not in itself constitute grounds for a higher remuneration rate.

3.2.1.2 Restrictions on the employment of the same person in different Projects or simultaneously by the Consortium Leader and a Consortium Member

In order for expenditure relating to the remuneration of a particular person as Project staff to be considered eligible, the following conditions, at a minimum, must be met:

- the individual's commitment to carrying out tasks within the Project and the resulting workload **ensure that all tasks entrusted to that person can be carried out correctly and effectively**;
- is calculated and paid in accordance with the law;
- in the case of a person employed by both the Consortium Leader and the Consortium Member(s), the remuneration (eligible cost) of that person under the Project may **be paid by only one of these entities**.

3.2.2 Drug

The Projects of Clinical Trial for Medicinal products **<u>are not</u>** eligible for funding under this Call for Proposals.

Under the Project, within the 'Drug' cost category, only the costs of Medicinal products and other substances necessary for carrying out a Medical procedure are eligible, provided that their use forms part of that procedure, in accordance with the Call for proposals documentation.

Funding for costs in this category is permitted only to the extent necessary to carry out the Research experiment. The subject of the Project must not be the assessment of the efficacy, safety or other properties of a medicinal product. Medicinal products may only be used as part of standard medical practice within the framework of the Medical procedure carried out under the Project. Where the purchase of medicinal products and substances necessary for carrying out a Medical procedure and available on the market is

planned, their name, technical specifications and details identifying the manufacturer or supplier must be specified in the budget.

It is possible for Medicinal products and substances necessary for carrying out a Medical procedure to be supplied free of charge by an external organization. Such an entity may be classified as a subcontractor or a Consortium Member, depending on the nature of the collaboration and the extent of its involvement in the Project. The choice between being classified as a subcontractor or a Consortium Member depends on the scope of responsibilities and the level of involvement in the Project. A subcontractor carries out the tasks specified in the Agreement on behalf of the Applicant, whilst a Consortium Member is a partner who participates in the implementation of the Project on an equal footing.

3.2.3 Medical service

Under this category, eligible costs are those relating to medical services provided by the Single-entity Applicant, the Consortium Leader or a Consortium Member(s), i.e. covering medical activities carried out as part of the Research experiment for the benefit of a participant in the Research experiment, including, for example:

- costs of diagnostic tests (e.g. laboratory, imaging, and genetic tests) as set out in the Protocol;
- hospitalization costs;
- consultations, advice and outpatient appointments;
- costs of Medical procedures.

3.2.4 Other

Under the Project, it is possible to budget for costs relating to:

- preparing the research, including Standard Operating Procedures (SOPs), compiling the full set of research documentation, and covering the fees for the Bioethics Committee's opinion;
- conducting the research, such as: the purchase and maintenance of the Case Report

Form (CRF)[5], the purchase of biostatistical software, and other IT systems supporting Project management, provided that the justification for their purchase is demonstrated;

- costs associated with disseminating research results, including: publication costs in academic journals, costs associated with organizing conferences, and costs associated with attending conferences (registration fees, travel and accommodation expenses);
- costs of measures aimed at improving the recruitment and retention of participants in the Research experiment;
- information and promotional costs relating to the research component of the Project;
- maintenance services and repair costs;
- transport services;
- costs of training relating to the role performed within the Project;
- costs of carrying out an external audit in accordance with the 'Guidelines for Auditors of Projects Funded by the Medical Research Agency', set out in Appendix 11 to the Rules and Regulations;
- costs of biobanking Biological material during the course of the Project – i.e. the costs of activities carried out in accordance with the biobank's Standard Operating Procedures (SOPs), such as: the collection of Biological material, its transfer to the biobank and its storage in a biobank operating in accordance with the Quality Standards for Polish Biobanks, version 2.00 (SJBP 2.0, 2021)[6] or in accordance with ISO 20387-2018 or a later version of this standard confirmed by a certificate (all costs associated with the biobanking process must be planned for, e.g. staff remuneration, consumables necessary for the collection of Material, sample

[5]Where an eCRF provided by the Agency is used, the costs of purchasing the eCRF constitute an ineligible cost.
[6]Quality Standards for Polish Biobanks v. 2.00 (2021)
https://wydawnictwo.umw.edu.pl/upload/files/standardy_jakosci_dla_biobankow_polskich_2.0.pdf

transport costs, storage costs depending on the number of samples planned for biobanking, etc.) carried out pursuant to the Agreement on the collection, storage, safeguarding, transfer and provision of access to Material, including Biological material for the purposes of future scientific or research and development studies, constituting Appendix 4 to the Rules and Regulations.

In the absence of the above certificates (ISO 20387-2018 or a later version of this standard, or SJBP 2.0), the Agency accepts the biobank's declaration of compliance with SJBP 2.0, 2021, and recognizes the costs incurred as eligible. However, the biobank is required to obtain a Certificate of Compliance with SJBP 2.0, 2021 (or, alternatively, an ISO 20387-2018 certificate or a later version of that standard) as soon as possible, and no later than the completion of the Project.

If the biobank fails to obtain one of the documents listed by the time the Project is completed (regardless of the reason), the costs of biobanking the Biological material will be deemed ineligible.

Note:

If biobanking is discontinued during the Project or fewer samples are biobanked than originally planned, it will not be possible to reallocate the funds for another purpose. In such a case, any unspent budget funds earmarked for biobanking will be **returned to** the Medical Research Agency.

If the software or systems (including licences) are not used throughout the entire duration of the Project, the eligible costs shall be deemed to be the depreciation costs corresponding to the duration of the Project, calculated in accordance with accounting regulations.

If the economic useful life of intangible assets (including software or systems and licences) extends beyond the Project implementation period, the depreciation costs corresponding to the Project implementation period, calculated in accordance with accounting regulations, shall be deemed eligible costs.

Depreciation costs relating to intangible assets are eligible for funding provided that all of the following conditions are met:

1) relate to the intangible assets recorded by the entity that purchased them;
2) are used directly to achieve the Project's objectives;
3) relate exclusively to the duration of the Project;
4) have been written off in accordance with the relevant legal provisions;
5) total cost of acquiring amortized intangible assets was not shown in the Application as a separate budget item;
6) purchase of amortized intangible assets was not financed from public funds derived from other sources or under other Projects;
7) are allocated on a pro rata basis depending on the extent to which the intangible assets are used in the Project;
8) the depreciation period, rate and method were determined on the basis of objective criteria, rather than with a view to maximizing the recognition of costs under the Project.

3.2.5 Specialist services commissioned

Within this category, costs relating to the implementation of substantive activities by external entities are eligible, e.g.:

- the costs of entrusting a healthcare provider with the recruitment of participants for the Research experiment;
- the costs of carrying out the Medical procedures set out in the research Protocol by the centre acting as a subcontractor;
- the costs of external, expert and consultancy services.

Expenditure relating to the commissioning of a specialist service may constitute eligible expenditure, provided that it has been included in the budget of the Application.

The actual performance of the commissioned specialist service must be documented in accordance with the contract concluded with the subcontractor, e.g. by means of a written handover report, a certificate of acceptance of the work carried out, etc.

It is not permissible for the Consortium Leader to commission a specialist service from Consortium Members, or vice versa. The tasks carried out under the Project must be set out in the Consortium Agreement, and no other civil law contracts relating to this Project may be entered into between the members of the Consortium.

Where the Beneficiary commissions a Subcontractor to provide a specialist service as part of the Project, the Beneficiary undertakes to provide all documents necessary to verify the eligibility of expenditure.

In justified cases and with the Agency's consent, the Beneficiary may, during the implementation of the Project, use the services of a Subcontractor or Subcontractors established outside the Republic of Poland.

3.2.6 Insurance costs

Within this category, provision should be made for costs relating to compulsory third-party liability insurance for the entity conducting the medical experiment (Research experiment).

3.2.7 Medical device and *in vitro* diagnostic medical device

The costs of Medical devices and *in vitro* diagnostic medical devices are eligible only in the case of devices that have been placed on the market and are used in accordance with their intended purpose.

Under this Call for Proposals, funding **is not available** for Clinical Trial Projects for Medical devices which are aimed at assessing the efficacy or safety of a device that does not bear the CE mark, or of a device that bears the CE mark but is being used for a purpose other than that intended by the manufacturer.

3.2.8 Involvement of the CRO

Under this category, the costs of CRO services are eligible, including, amongst other things, the development of quality control methods, etc.

3.2.9 Purchase of medical equipment, including research infrastructure

Under this category, costs relating to apparatus and equipment used in the implementation

of the Project are considered eligible.

If the equipment and apparatus are not used throughout the entire duration of the Project, the depreciation costs corresponding to the Project's duration, calculated in accordance with accounting regulations, shall be regarded as eligible costs.

Depreciation costs relating to fixed assets are eligible for funding provided that all of the following conditions are met:

1) relate to fixed assets recorded in the fixed asset register of the entity that purchased them;
2) are used directly to achieve the Project's objectives;
3) relate exclusively to the duration of the Project;
4) were carried out in accordance with the relevant legal provisions;
5) the total cost of purchasing the depreciable fixed asset was not specified in the Application as a separate budget item;
6) the purchase of the depreciable fixed asset was not financed from public funds derived from other sources or under other Projects;
7) are allocated on a pro rata basis depending on the use of the fixed asset within the Project;
8) depreciation period, rate and method were determined on the basis of objective criteria, rather than with a view to maximizing the recognition of costs under the Project.

Investment purchases may also be accounted for through leasing, in which case the capital component of the lease instalment is an eligible cost (in proportion to the extent to which the equipment is used in the implementation of the Project), whilst the interest component, together with insurance, guarantees and other charges, constitutes an ineligible expense and is covered from the Beneficiary's own funds.

In order to be considered eligible, the above types of costs must:

- be scheduled as part of the Application;
- be necessary for the implementation of the Project;
- be incurred in connection with its implementation.

When drawing up the budget, the Applicant is required to use rates no higher than those set out in the Catalogue of the Most Common Costs, which forms Appendix 5 to these Rules and Regulations. Where justified, the rates set out in the Catalogue may be subject to change during the course of the Project

3.2.10 Indirect costs

Indirect costs are the administrative costs associated with the running of the Project, in particular:

- costs of the salary of the coordinator or administrative manager (this category does not include the Head of Research experiment or the Project Manager) and other staff directly involved in the administrative management and financial settlement of the Project;
- management costs (remuneration costs for persons authorized to represent the entity whose duties are not exclusively assigned to the Project, e.g. the entity's head);
- staff costs for support staff (legal, HR, finance, accounting, administrative and secretarial staff, including regular cooperation with the Agency regarding reporting and the day-to-day control and monitoring of the Project);
- expenses relating to the opening or maintenance of a subaccount within a bank account or a separate bank account set up specifically for the Project;
- information and promotional activities for the Project – not related to the research component of the Project – in accordance with the provisions of the Co-financing Agreement concerning information and promotion, including the purchase of stickers for labelling fixed assets and equipment with a value exceeding PLN 10,000 (in words: ten thousand zlotys), funded under the Project, which are to be entered into the Beneficiary's fixed assets and equipment register;

- charges for electricity, heating, gas and water; transmission charges; sewage charges;
- costs of postal, telephone, Internet and courier services relating to the conduct of the Research experiment and the administrative management of the Project;
- office costs relating to the administrative management of the Project (e.g. purchase of office supplies and stationery, the cost of document reproduction services, etc.);
- costs of ensuring proper performance of the Co-financing Agreement;
- property insurance costs (with the exception of the cost of civil liability insurance for the Investigator and the Beneficiary in respect of damage caused in connection with the conduct of the Research experiment, which constitutes a direct cost).

Indirect costs comprise a flat-rate of 15 per cent of the actual costs[7], less the costs associated with the purchase of research infrastructure/equipment and the costs of commissioned technical services and the involvement of a CRO. The specified percentage is calculated on the basis of the total for the following cost categories: *Remuneration*, *Medical service*, *Medicines*, *Insurance costs*, *Medical devices*, *Other*.

Indirect costs are treated as expenses incurred. The Beneficiary is not required to collect or document accounting records to confirm that expenditure, which has been accounted for as indirect costs, has been incurred.

3.3. Catalogue of ineligible costs

In Research experiment Projects funded by the Agency, it is not possible to budget for the following under actual costs:

- standard office equipment, including desks, chairs and lamps;
- equipping workstations, including laptops and printers;
- Projection screens, multimedia Projectors;
- printing and photocopying services;
- bank charges, currency conversion costs, exchange rate differences;

[7]Understood as the costs actually incurred.

- costs of renting and maintaining buildings and adapting premises;
- contributions made by employers in accordance with the Act of 27 August 1997 on vocational and social rehabilitation and the employment of people with disabilities, to the State Fund for the Rehabilitation of People with Disabilities (PFRON);
- benefits funded from the Company Social Benefits Fund (ZFŚS) for staff involved in the Project;
- long-service awards and severance pays for staff assigned to the Project;
- training not related to the role performed within the Project;
- IT tools that are not directly related to the implementation of the Project;
- the cost of storing Biological material collected from participants in the Research experiment in a biobank following the completion of the Project;
- the cost of storing, in a biobank, Biological material collected from participants in the Research experiment during the course of the Project, if the biobank does not hold and does not obtain a Certificate of Compliance with SJBP 2.0, 2021 (or, alternatively, an ISO 20387-2018 certificate or a later version of that standard) during the duration of the Project;
- the cost of storing, in a Biobank, Biological material collected on behalf of the Beneficiary for its future scientific purposes other than those set out in the Research Protocol for the proposed Project, from participants in the Research experiment during the course of that Project.

3.4 Award of contracts under the Project

The Beneficiary's purchases of goods and services are made in accordance with the legal provisions applicable to the entity in question, in particular the Public Procurement Act.

All expenditure must be incurred in accordance with the principles of fair competition, transparency, equal treatment of subcontractors, proportionality and the absence of any conflict of interest, understood as a lack of impartiality and objectivity in connection with the performance of the Co-financing Agreement.

The Beneficiary is obliged to retain, in a manner that ensures adequate security, all data relating to the implementation of the Project, in particular documentation relating to financial and technical management or procedures for entering into contracts with subcontractors, for the duration of the Project and for at least 5 years from the date of approval of the Final Report on the implementation of the Project.

If the entity carrying out the contract is not subject to the Public Procurement Law, or if (in the case of entities subject to the Public Procurement Law) the contract is below the thresholds specified in Article 2(1)(1) of the aforementioned Act, as well as in the case of other contracts for which the application of the Public Procurement Law is excluded, the Beneficiary is obliged to apply internal regulations, provided that they ensure, at a minimum, compliance with the conditions set out in the Call for Proposals Rules and Regulations, and the Co-financing Agreement. In the absence of internal regulations, or where such regulations do not provide for the use of competitive procedures for the selection of a contractor or do not ensure, at the very least, compliance with the conditions set out in the Call for Proposals Rules and Regulations, and the Co-financing Agreement, for procurement with a value equal to or greater than PLN 80,000 net (in words: eighty thousand zlotys), the Beneficiary is obliged to carry out a market survey in accordance with the rules set out in the Rules and Regulations, and the Co-financing Agreement.

The market research procedure should ensure that contracts are awarded at market price, i.e. the price most commonly offered on the market or the most likely purchase price for goods or services on the relevant market. The market research procedure must be applied to purchases of goods and services with a value of PLN 80,000 net (in words: eighty thousand zlotys) or more. It sets out the minimum requirements concerning, amongst other things, the manner in which information on contracts and their completion dates is to be made public, whilst leaving the Beneficiary free to determine the details relating to the evaluation and selection of contractors. The Beneficiary may therefore adapt the method (procedure) for conducting the procurement process to its own needs and the specific nature of the procurement, provided that this does not conflict with the requirements of the market research procedure and the principles of competitive spending, as set out in

the Project Co-financing Agreement. As part of the market research procedure, the Beneficiary is required, in particular, to:

1) publishing the request for proposals on at least the Beneficiary's website and sending the request for proposals to at least three potential contractors. The minimum deadline for submitting proposals must not be less than 7 days from the date on which the request is published on the website or sent to contractors. Where there are no three potential contractors on the market, the Beneficiary is required to provide a justification setting out the objective grounds confirming this fact;
2) it is also permissible to obtain quotations in the form of price lists from the websites of potential contractors. The Beneficiary is required to obtain at least three price lists.

When carrying out a market research procedure, the following requirements must be taken into account:

- the price (cost) must be the sole criterion or one of the criteria for evaluating proposals; that is to say, one or more criteria may be used to evaluate proposals, but the price (cost) must always be included amongst them;
- if no proposal is submitted during the procedure, the Beneficiary should repeat the procedure; and if, as a result of this, no proposal is received either, the Beneficiary should select a contractor by single-source procurement (it is permissible to award a contract under single-source procurement following the first procedure, but only in situations where, for example, the time required to repeat the procedure would have adverse effects on the Project; these should be documented, e.g. in the form of a note, and retained in the procurement procedure documentation in the event of an audit). In such a situation, the conclusion of a single-source procurement contract should be preceded by negotiations with the contractor.

It is not necessary to carry out a market research procedure where all of the following conditions are met:

- the contract relates to the services of investigators and medical staff (e.g. doctors, nurses, laboratory technicians);

- the service is commissioned to the Beneficiary's own staff (meaning persons linked to those entities by an employment relationship, as well as by civil-law contracts, including service contracts), and the subject matter of the contract does not relate to activities of the same nature as those which the employee carries out under their employment relationship with the Beneficiary;
- the cost of the service does not exceed market prices and the staff costs applied by the Beneficiary when deploying staff to carry out tasks analogous to the subject of the contract.

One of the elements of expenditure control within the Project is the verification of the correctness of contracts awarded under the Project. As part of the audit, it is verified whether the procurement procedure for the Project was conducted in a manner that ensured, in particular, compliance with the principles of fair competition and equal treatment of contractors.

The correct application of the appropriate procedure, depending on the value of the contract, is as follows:

Public procurement value	**< PLN 80,000 net**	**≥ PLN 80,000 net < PLN 170,000**	**≥ the equivalent of PLN 170,000 net[8]**
Type of procedure	**In accordance with the internal procedures of** the Beneficiary and the Consortium Member (where applicable). If not applicable – ensure that expenditure is	**Market research – documenting** the market research in the manner specified in the Rules and Regulations, of the relevant Call for Proposals and the Co-financing Agreement.	Public Procurement Law **– the application of** the procedures set out in the Public Procurement Law by entities obliged to comply with the Act. **Market research –** for entities not required

[8] In accordance with Article 2(1)(1) of the Public Procurement Act.

	incurred in a transparent, competitive, rational and efficient manner, whilst adhering to the principles of achieving the best results from the given expenditure.		to comply with the Public Procurement Act.

It should be borne in mind that no legal provisions that may apply in connection with the implementation and settlement of Projects funded by MRA set out rules regarding the calculation (including the adjustment) of ineligible expenditure arising from identified irregularities in this area. It is therefore appropriate to adopt measures analogous to those in the legislation governing similar Projects, involving **the imposition of financial corrections in connection with irregularities in the award of public contracts, by** reducing the value of eligible expenditure by an amount calculated using the percentage rate provided for in those provisions.

With regard to funded Projects, MRA will apply, on a supplementary basis, the financial correction rates set out in points (No.) 18, 21 and 22 of the Appendix – Percentage rates of financial corrections and reductions for specific categories of individual irregularities applied in contracts in accordance with the Guidelines of the Minister for Funds and Regional Policy

of 4 July 2023 concerning the method of correcting irregularities for the years 2021–2027), relating to the following infringements (irregularities) associated with a breach of the principles of fair competition:

No.	Type of Irregularity	National law on public procurement	European Union law and the case law of the Court of Justice of the European Union (CJEU)	Description of irregularities	Percentage rate
18	Any previous improper relations between candidates or tenderers and the contracting authority	- Articles 16 and 17(2) and (3) - Articles 84 and 85 of the Public Procurement Act	- Articles 3 and 30(2) of Directive 2014/23/EU, - Article 18(1): - Articles 40 and 41 of Directive 2014/24/EU, - Articles 36(1) and 59 of Directive 2014/25/EU, - the judgment of the CJEU in joined cases C-21/03 and C-34/03	Where advice previously provided to the contracting authority by a tenderer distorts competition or results in a breach of the principles of non-discrimination, equal treatment and transparency under the conditions set out in Articles 40 and 41 of Directive 2014/24/EU	25%
21	A conflict of interest affecting the outcome of a procurement	- Article 17(3),	- Article 35 of Directive 2014/23/EU,	Any instance in which an undisclosed or inadequately	100%

	procedure	- Articles 52 and 56, - Article 109(1)(6), - Article 332, - Article 335(3) of the Public Procurement Law,	- Article 24 of Directive 2014/24/EU, - Article 42 of Directive 2014/25/EU, - Judgment of the CJEU in Case C-538/13, paragraphs 31–47	mitigated conflict of interest has been identified, in accordance with Article 24 of Directive 2014/24/EU (or Article 35 of Directive 2014/23/EU, or Article 42 of Directive 2014/25/EU), and the tenderer in question has been awarded the contract or contracts in question	
22	Bid rigging / anticompetitive agreement (as established by the President of the Office of Competition and Consumer Protection, a court, or another competent authority). A bid-rigging scheme occurs when a group of enterprises agrees to raise prices or lower the quality of goods, works or services offered in the context of a procurement procedure or procedures. Failure to apply the correction is justified where the tenderers involved in the bid-rigging scheme	- Article 56 of the Public Procurement Law, - Article 6(1) of the Act of 16 February 2007 on the Protection of Competition and Consumers	- Article 35 of Directive 2014/23/EU, - Article 24 of Directive 2014/24/EU, - Article 42 of Directive 2014/25/EU	Case 1a: the tenderers involved in the bid-rigging scheme acted without the support of any person acting within the management and control system or the contracting authority, and the contractor involved in the bid-rigging scheme or the agreement restricting competition was awarded the contract or contracts in question. Case 1b: if only contractors involved in a bid-rigging scheme took part in the procurement procedure, this constitutes a serious distortion of competition.	10% 25%

	acted without the support of a person working within the contracting authority, and none of the enterprises involved in the bid-rigging scheme was awarded the contract or contracts in question.			Case 2: a person acting within the management and control system or the contracting authority took part in a bid-rigging scheme by providing support to the tenderers involved in the scheme, and the subcontractor involved in that scheme was awarded the contract or contracts in question. In such a case, there is an abuse of position or a conflict of interest on the part of a person acting within the management and control system who provides support to subcontractors involved in a bid-rigging scheme or to the contracting authority.	100%

At the same time, it should be borne in mind that the corrections described above **will apply not only to public contracts awarded under the Public Procurement Law** (as provided for in the aforementioned Guidelines on the method of correcting irregularities for the years 2021–2027), **but also to contracts to which that Act does not apply** (for contracts below the thresholds referred to in Article 2(1)(1) of the Public Procurement Act and for other contracts in respect of which the application of the Public Procurement Act is excluded, as well as in cases where the Beneficiary is not obliged to apply the Public Procurement Act).

3.5 Disbursement method

The grant awarded is paid to beneficiaries in the form of an advance or a reimbursement (provided that the first instalment of the grant is always paid as an advance), in the amount specified in the Payment schedule. Payment of the grant is conditional upon the Agency receiving the funds referred to in **Article 28(1)(3) of the Act.** The Payment schedule sets out the Projected amounts and dates for the payment of advances or refunds, the payment of which is subject to the availability of the aforementioned funds in the relevant financial year. Should the above-mentioned funds not be available, the Beneficiary is required, at the Agency's request, to submit a revised Payment schedule that takes into account the Agency's current financial capacity.

Funds are paid into a separate bank account specified in the Co-financing Agreement. **This account must bear interest**. In the event of a change to the bank account number, the Beneficiary is required to notify the Agency of such a change without delay in writing (which also includes electronic form with a qualified electronic signature, in a format compliant with the eIDAS Regulation (EU) No 910/2014; using a graphic symbol).

Subject to the exclusions set out below, the first advance payment will be made once the Single-entity Applicant or Consortium Leader has established and provided the Agency with appropriate and valid security for claims arising from or in connection with the Co-financing Agreement, valid for the duration of the Project and for a period of 5 years from the date of its completion as specified in the Grant application. The provision of a security by the Consortium Leader does not alter the principle that the members of the Consortium are jointly and severally liable to the Agency.

The obligation set out above to provide a performance guarantee in respect of the payment of any sums arising from or in connection with the Co-financing Agreement **does not apply**, as appropriate, to:

- **A Single-entity Applicant** that is **a public finance sector entity within the meaning of Article 9 of the Act of 27 August 2009 on Public Finance,** a research institute **within the meaning of Article 1(1) of the Act of 30 April 2010 on Research**

Institutes, or an institute operating within the Łukasiewicz Research Network**, as referred to in Article 1(1)(2) of the Act of 21 February 2019 on the Łukasiewicz Research Network**

- **The Consortium Leader, where all entities comprising the Consortium are public finance sector entities within** the meaning of Article 9 of the Act of 27 August 2009 on Public Finance, or **research institutes within** the meaning of Article 1(1) of the Act of 30 April 2010 on research institutes, or **institutes operating within the Łukasiewicz Research Network**, as referred to in Article 1(1)(2) of the Act of 21 February 2019 on the Łukasiewicz Research Network.

Subject to the differing provisions set out above, where there is an obligation to provide security, such security shall be provided, at the Beneficiary's discretion, in the form of:

1) a declaration by the Single-entity Applicant/Consortium Leader agreeing to be subject to immediate enforcement proceedings by the Agency pursuant to Article 777(1)(5) of the Act of 17 November 1964 – *the Code of Civil Procedure*, pursuant to which the above-mentioned entities shall submit to enforcement against all their assets up to a maximum amount of 110 per cent of the grant awarded, or
2) *a blank promissory note* issued by the Single-entity Applicant or the Consortium Leader, bearing the clause 'not on commission' and a notarised signature, together with a promissory note declaration bearing a notarised signature, which shall specify the right to fill in the amount on the promissory note up to 110 per cent of the grant awarded,
3) essentially in accordance with the templates set out in the Appendixes to the Agreement.

The Agency may, in the event of reasonable doubts as to the proper performance of the Contract or following an analysis, require the Single-entity Applicant or the Consortium Leader to provide additional security for the performance of the Contract in the specified form and within the specified time limit, which shall not be less than 14 days, irrespective of whether the entity is eligible for exemption in this regard.

As a general rule, further advance payments or refunds are made in accordance with the

approved Payment schedule, following successful verification of the interim report.

In the case of expenditure settlement by way of reimbursement, the condition for the payment of the grant is the Agency's approval of the eligible expenditure incurred by the Beneficiary and the Consortium Members (where applicable), and the Agency's verification of the justification for continuing the Project, based, amongst other things, on the progress made to date in implementing the Project, as set out in the Report.

Detailed provisions regarding any settlements or recourse claims between the Consortium Leader and the Consortium Members, or between the Consortium Members individually, shall be set out by the parties to the Consortium Agreement in the text thereof; however, they undertake to ensure that the agreed contractual provisions—including, amongst other things, those relating to settlement and recourse—do not undermine the essence of joint and several liability towards MRA, nor do they conflict with the provisions of the Rules and Regulations and appendixes, or with the provisions of the Co-financing Agreement.

3.6 Settlement rules

A Beneficiary who has been awarded funding for the implementation of the Project shall submit reports on the use of funds, containing the following information:

- a description of the progress made on individual tasks, with reference to the activities carried out, and the Milestones set out in the Application;
- financial progress on the Project;
- justification for the continued implementation of the Project and activities planned for the next reporting period;
- the extent to which the indicators have been achieved;
- description of the problems that arose during the Project and the remedial measures taken.

Irrespective of the progress reports, the Beneficiary is required to keep the information on the extent to which the indicators have been achieved up to date and to obtain the relevant authorizations to carry out the study within the 'HERA' (Schedules, Outcomes, Implementation, Allocation) system.

The verification of declared expenditure is carried out on the basis of the actual progress made in implementing the Project and the extent to which the set indicators and Milestones have been achieved.

Reports must be submitted for the reporting periods specified in the Payment schedule. The deadlines for submitting reports are set out in the Co-financing Agreement. The report comprises a substantive section and a financial section, including, amongst other things, a summary of accounting documents relating to goods or services purchased as part of the Project.

Reports are submitted to the Agency via the ICT system, unless the President directs otherwise. The first Report covers a period of 3 months from the date on which the Project commences, as specified in the Application, or, if the Agreement is concluded after that date, from the date on which the Agreement is signed. Subsequent reports shall cover each subsequent six-month period until the completion of the Project.

A Beneficiary notified by MRA of errors or omissions in the submitted Report is obliged to rectify them within the time limit specified in the Agreement. MRA may make clerical or accounting corrections or amendments to the Report without the need for the Beneficiary's approval. The Agency shall inform the Beneficiary of the scope of the amendments and additions made. Failure by the Beneficiary to rectify any errors or omissions in the Report may result in its rejection and the suspension of the payment of funding. If the Project Beneficiary repeatedly makes the same errors in the implementation and settlement of the Project, the President may terminate the Agreement or deem part of the expenditure, including in particular that relating to Project Management, to be ineligible.

Proof of the cost incurred is an invoice that has been issued and paid, or another accounting document of equivalent evidentiary value.

The Beneficiary, including Consortium Members (where applicable), **must retain the originals of documents supporting the expenditure incurred** in connection with the implementation of the Project. Any expenditure incurred by the Beneficiary, including a Consortium Member (where applicable), must be supported by an appropriate accounting

document.

In the case of invoices in the KSeF system, it is necessary to provide information enabling access to a structured invoice in accordance with the provisions of the Regulation of the Minister of Finance and Economy of 12 December 2025 on the use of the National e-Invoice System.

Where outsourced tasks under the Project are performed by Subcontractors, proof of expenditure shall, as a rule, take the form of an invoice for the total amount of the goods/services/supplies, specifying, as applicable, the unit price of the relevant goods/services/supplies.

In the case of Project staff, the work carried out on the Project must be documented in such a way as to enable the expenditure to be deemed eligible; this may take the form of, amongst other things:

- payroll records (in the case of an employment relationship);
- timesheets detailing the tasks performed (for staff who are paid on an hourly basis as part of the funded Project);
- account;
- a list of duties under the Project and a handover report (contract for services/contract for specific work). The acceptance report for the contract for services must include a detailed breakdown of the subcontractor's working hours, together with an allocation to the specific tasks arising from that contract;
- time records with a description of the tasks carried out (self-employment).

For the purposes of determining the eligibility of a cost in terms of timing, the date of payment shall be decisive.

In the course of the financial settlement of the Project, MRA may request the submission of all or selected source documents.

The original accounting document must be **correctly described** so that it can be linked to an expenditure incurred for the purposes of the Project. This description should include at least the following information:

- the Agreement number,
- date of issue of the document;
- cost category;
- the number of the task being carried out as part of the Project and the budget line;
- the amount of eligible expenditure and the amount of value-added tax.

The Beneficiary is required to keep separate, transparent records of the Project's expenditure in such a way that individual operations relating to the Project can be identified, excluding indirect costs. This obligation applies to each member of the Consortium in respect of that part of the Project for which the relevant Consortium Member is responsible. Entities which are not required to keep any accounting records under the applicable legislation are obliged, for the purposes of the Project, **to maintain separate accounting records of documents** relating to expenditure incurred in connection with the implementation of the Project.

The Agency is entitled to inspect the Project documentation at any time and at any phase or stage of the Project's implementation, and for a period of 5 years from the date of approval of the Final Report. The President, in accordance with Article 22 of the Act, on the basis of an audit carried out or an analysis of the content of the interim report, may, after consulting the Board, suspend, interrupt or terminate the funding of the Project.

- **A condition for the settlement of the Project is the submission, within 90 days of the Project completion date, via the ICT system (unless the President of MRA decides otherwise), a final report on the implementation of the Project covering both substantive and financial aspects, together with a Research Experiment Report, and their approval by the Agency within the timeframe specified in the Co-financing Agreement.**

  Important: the deadline for incurring expenditure relating to the Project is the Project completion date.

Any portion of the funding not utilized by the Beneficiary must be repaid to the Agency's bank account upon completion of the Project, within the timeframe and in accordance with the terms set out in the Agreement.

3.6.1 Principles of financial settlements between Consortium Members

Expenditure incurred under the Project by a Consortium Member selected in breach of subsection 2.5.2 *Rules for the formation of the Consortium* may be deemed ineligible by MRA.

It is not permitted for the Consortium Leader and the Consortium Members to commission one another to purchase goods or services. A situation in which there is a conflict of interest between the Consortium Leader and a Consortium Member is unacceptable. A conflict of interest is defined as a situation in which the same person represents two parties bound by a contract and, within the framework of that contract, carries out legal and factual acts relating to the performance of that contract.

The Consortium Leader may transfer funds to Consortium Members to cover the costs they incur. These costs arise from the performance of the tasks set out in the Application. The performance of the above tasks does not constitute the provision of services to the Consortium Leader.

A Consortium Member is obliged to incur expenditure in accordance with the Rules and Regulations.

All payments made in connection with the implementation of the Project between the Consortium Leader and the Consortium Members shall be made via bank accounts held by the entities forming the Consortium and designated specifically for the Project.

Costs incurred by a Consortium Member may be eligible provided they are in accordance with the approved Application and are necessary for the achievement of the Project's objectives.

Expenditure incurred by the Consortium Members must be incurred in accordance with the principles of reasonable financial management, in particular the best possible cost-benefit ratio.

The contribution of the Consortium Members, consisting in particular of the provision of human, organizational, technical or financial resources, must be commensurate with the objectives of the Project.

3.6.2 Principles of settlement with a foreign subcontractor

Under Projects funded by MRA, expenditure incurred in connection with foreign subcontracting may be considered eligible in the following cases:

- performance of tasks/research on behalf of Research experiment participant within the Project, who is entitled to healthcare benefits within the Republic of Poland (RP);
- performance of diagnostic analyses (laboratory, imaging, etc.) and biostatistical analyses of study results, including personnel costs incurred in connection with such analyses.

Research involving Research experiment participants who are not entitled to benefits in the Republic of Poland, in respect of Medical procedures carried out directly on the participant, may not be funded from the Project's resources, and such expenditure will be deemed ineligible.

It is permissible to transfer, free of charge, items such as software, IT equipment for conducting research, and analytical tools developed as part of the Project to a foreign centre for the purpose of implementing the Project. The cost of transporting individual components may be included in the Project budget.

3.7 Biobanking of Biological Material under the Agreement on the Collection, Storage, Safeguarding, Transfer and Sharing of Material, including Biological material for the purposes of future scientific research or research and development activities.

Where the Applicant plans, as part of the Project, to collect Biological material (peripheral whole blood samples) from research participants for the purpose of carrying out the procedures set out in the Research Experiment Protocol, provided that the research participant gives their informed consent, the Applicant is required to collect one additional sample of Biological material and to obtain a completed participant questionnaire from each participant for submission to the biobank. Quantity of banked blood should be sufficient to enable the sequencing of the donor's genome.

Where the Applicant does not intend to collect Biological material, or where none of the participants has given their informed and voluntary consent to this, the applicant is exempt from the obligation to biobank the Material.

An Applicant collecting a sample of Biological material from a participant is required to:

- submit a declaration (in the Application) that, in the case of biobanking, this will take place at a biobank operating in accordance with the Quality Standards for Polish Biobanks v. 2.00 (2021)[9] and any updates thereto, or in accordance with ISO 20387-2018 or a later version of that standard confirmed by a certificate, subject to the provisions of section 3.3:
  - The Beneficiary is required to adopt the Standard Operating Procedures (SOPs) of the biobank where the collected Biological material samples will be stored;
- obtain the participant's informed and voluntary consent to the banking of samples of their Biological material and their subsequent use for future scientific research or research and development;
- include in the budget of the Application the costs of collecting, transferring and biobanking a single sample of Biological material collected from each participant enrolled in the Research experiment:
  - Biological material from a single participant (1 sample) should be divided into 4 *tubes/vials*,
  - The Agency shall cover the costs of storing samples of Biological material in the biobank for the duration of the Project, assuming an annual cost of no more than PLN 45.00 gross per test tube/vial (PLN 180.00 for 4 test tubes/vials = 1 sample),
  - The Beneficiary is obliged to cover the costs of storing the sample for consecutive three years following the completion of the Project.

Appendixes 4a, 4b and 4c to the Rules and Regulations set out the templates for the Agreement on the collection, storage, safeguarding, transfer and provision of Material,

[9]Quality Standards for Polish Biobanks v. 2.00 (2021)
https://wydawnictwo.umw.edu.pl/upload/files/standardy_jakosci_dla_biobankow_polskich_2.0.pdf

including Biological material, for the purposes of future scientific or research and development studies, and the template for 'Information for participants, together with a form of informed consent for an optional study involving the collection, storage and use of Biological material, including medical data and genetic data, for future scientific or research and development purposes', as well as a template for the research participant questionnaire. The Beneficiary is obliged to enter into a contract in accordance with the above model contracts and to obtain the participant's informed consent to biobanking, the wording of which must, in all Material respects, correspond to the template provided by MRA. Once a contract has been concluded with an external biobank or a biobank located within the Consortium Member's organization, the Beneficiary is required to notify the Agency of this fact by sending a copy of the contract. Where biobanking is carried out at an external biobank or one located within the Consortium Member's organization, the Consortium Leader is required to enter into a personal data processing agreement with the Agency, the terms of which must, in all Material respects, be consistent with the model set out in Appendix 4d to the Rules and Regulations.

Note:

The above document templates relate ONLY to the biobanking procedure for Biological material collected under the Agreement on the collection, storage, preservation, transfer and provision of access to Material, including Biological material for the purposes of future scientific or research and development studies, which forms Appendix 4 to the Rules and Regulations. If the Applicant, as part of the Clinical Trial Protocol being carried out, plans to biobank blood or other types of material for its own future scientific research, it is required to obtain informed consent from the research participants and to draw up the remaining required documentation on separate forms, prepared independently for the purposes of the research in question, and to finance this outside the scope of the Project.

In the case of biobanking of Biological material necessary to achieve the Project's objectives (e.g. biobanking of tumour tissue), the Beneficiary is required to obtain additional documents from the participant, in accordance with the purpose of the research

and the procedures of the biobank in question.

The Applicant, as in the case of biobanking of Biological material collected under the Agreement on the Collection, Storage, Safeguarding, Transfer and Provision of Material, including Biological material for the purposes of future scientific or research and development studies, which constitutes Appendix 4 to the Rules and Regulations, undertakes to submit a declaration (in the Application) that, in the event of biobanking, this will take place in a biobank operating in accordance with the Quality Standards for Polish Biobanks v. 2.00 (2021)[10] and any updates thereto, or in accordance with ISO 20387-2018 or a later version of that standard confirmed by a certificate, subject to the provisions of section 3.3.

3.8 Research experiments completion

Every research experiment should be completed by drawing up a Research experiment report.

The Project must result in the publication of the results of the research conducted under the Project in a peer-reviewed scientific journal, or in the acceptance for publication of a manuscript presenting the results of such research by the journal's editorial board, no later than 6 months after the Project completion date. The publication or acceptance for publication should take place, for example, in one of the scientific journals included in the most recent, as at the date of publication of the results, *List of Scientific Journals and Peer-Reviewed Materials from International Conferences* published by the Minister of Science and Higher Education.

In justified cases, the Project implementation period may be extended by a total of no more than 12 months, upon a written request from the Beneficiary submitted to the Agency no later than 90 days before the end date of the Project implementation specified in the Application. The Agency may refuse to grant approval for an extension of the Project's implementation period without giving a reason.

[10]Quality Standards for Polish Biobanks v. 2.00 (2021)
https://wydawnictwo.umw.edu.pl/upload/files/standardy_jakosci_dla_biobankow_polskich_2.0.pdf

3.8.1 Research Experiment Report

A Research Experiment Report is a document describing a single Research experiment. The Agency recommends that, when drawing up the Research Experiment Report, it should be demonstrated that all the study procedures and objectives described in the Study Protocol were carried out as planned. In the event of any discrepancies, a detailed explanation is required. The Research Experiment Report should include information on, amongst other things, the aim and plan of the research, a description of the study population, the research methodology used, and an assessment of the efficacy and safety profile of the Medical procedure. The results of the research and the conclusions should be based on data from statistical analysis. The Beneficiary should specify the sample size included in the Project in relation to the number of the Research experiment participants planned in the Application, provide a statistical analysis (taking into account the methodology relating to the sample size in the analysis), conclusions regarding the endpoints specified in the Protocol, and the benefits for participants in the Research experiment and for the healthcare system. Furthermore, the Research experiment report should be prepared in accordance with the ICH Guideline for Structure and Content of Clinical Study Reports. In addition, the Beneficiary should provide MRA with a summary written in a way that is understandable to those without specialist knowledge. Generally speaking, the guidelines setting out the structure of the document are based on the principle known as the ‘information pyramid’, which involves creating the following sections/modules, starting with: the title, abstract, main text, tables, figures and case studies, and appendixes. In the case of attachments and large datasets, please provide a detailed reference to enable the information to be found easily.

4. Grant Application evaluation procedure

Every application submitted during the Call for proposals will be assessed, provided it has not been withdrawn from the call by the Applicant.

Applications are assessed by the Applications Evaluation Team appointed by the President, which comprises Agency staff or experts appointed by the President.

During the Applications' assessment procedure (formal evaluation, substantive evaluation), all or some of the Applications may be forwarded to:

- legal analyses;
- scientific analysis;
- statistical analysis;
- economic analysis.

It is not compulsory to carry out the above-mentioned analyses. Decisions on whether to refer an application to some or all types of analysis are taken by the Head of the Application Evaluation Team.

4.1 Formal Evaluation Procedure

MRA staff carry out the formal assessment of Applications. The formal assessment of the Application is carried out on the basis of the formal criteria set out in subsection 4.1.1. Formal Evaluation Criteria.

An Application is assessed favourably if it meets all the formal criteria.

In accordance with the information set out in subsection 4.1.1. Formal Evaluation Criteria: some omissions cannot be rectified. In the case of formal deficiencies that can be rectified, the Agency shall request that they be rectified within 7 days, failing which the Application will not be considered. The request will be sent to the Applicant via e-Delivery to the address for electronic service, or, if no such address is specified in the Application, to the address corresponding to the Applicant’s tax identification number (NIP); and where it is not possible to use the electronic service functionality, the public hybrid service shall apply).

Information regarding Applications that have passed the formal evaluation and have been forwarded for substantive evaluation will be published on the Agency's website.he following criteria are checked during the formal evaluation:

1. **The Application was submitted in the correct form and within the deadline via the ICT system. (YES/NO – REJECT THE APPLICATION)**
   (This criterion **cannot be supplemented**)

It will be verified whether the Application was submitted between 15 September 2026 at 12:00:00 and 17 November 2026 at 12:00:59 (Central European Time) in the form of an electronic document via the MRA ICT System, available at the web address https://konkurs.abm.gov.pl.

The date on which the electronic version of the Application is submitted via the ICT system shall be deemed to be the date of receipt of the Application.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

2. **The Application was submitted by the authorized entity or entities. (YES/NO – REQUEST FURTHER INFORMATION / NO – REJECT THE APPLICATION)**
   (This criterion **is subject to further clarification**)

A check is carried out to verify whether the Applicant is one of the entities specified in the list of entities authorized to submit an Application and whether it meets the conditions for the implementation of the Project.

The list of entities authorized to submit an Application is set out in Article 17(1)(1, 2, 3,

5)(a) of the Act and the Rules and Regulations.

At the same time, under this Call for Proposals, it is not possible to award funding that would constitute state aid as referred to in Article 107(1) of the Treaty on the Functioning of the European Union. Consequently, the verification criteria also include an assessment of whether the support requested for the implementation of the Project constitutes state aid for the Applicant. In view of the above, **the Agency may request the single-entity Applicant / Consortium Leader / Consortium Member(s) to submit documents in order to confirm that the support requested for the implementation of the Project does not constitute state aid for the Applicant, including** the submission of declarations, the template for which is set out in Appendix 10 to the Call for Proposals' Rules and Regulations, or PNT-01 reports on research and development (R&D) in accordance with the GUS template (submitted in .pdf format), as well as documents confirming the separation of economic and non-economic activities.

If, despite the Applicant having made the relevant declarations, it transpires that the funding for the implementation of the Project would constitute state aid for the Applicant, this will result in the formal criterion not being met.

The criterion may be supplemented with regard to documents confirming the entity's status. The opportunity to rectify the Application also includes the submission of additional documentation confirming the Applicant's eligibility to submit the Application and confirming that the grant awarded will not constitute state aid. At the stage of supplementing the documentation, it is not possible to change the Applicant, i.e. the Single-entity Applicant, the Consortium Leader or a Consortium Member.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

3. **The Application meets the following condition: there is no double funding from public funds for identical Projects – the tasks covered by the Grant Application are not funded under Projects financed by the Medical Research Agency or from other sources, e.g. the National Centre for Research and Development, the National Science Centre, etc. (YES/NO – REJECT THE APPLICATION)**

   (This criterion **cannot be supplemented**)

Applicants are required to submit a declaration stating that they have not received, and are not seeking, public funding from other sources (e.g. the National Centre for Research and Development, the National Science Centre, the National Health Fund) for the activities covered by the Application.

Funding may be provided **for the continuation of** Projects that were previously funded from other sources.

The statements submitted by the Applicant will be verified in accordance with the provisions of the Public Finance Act. Making the above declaration is understood to mean completing the relevant field in the 'Declaration' section of the Grant Application.

In addition, the submitted Applications will be assessed for similarity between the underlying assumptions of the Projects, based on publicly available Project databases and information on Projects funded by the Agency. Where the similarity assessment indicates that the tasks covered by the Grant Application are already financed under Projects funded by the Agency or from other sources, the formal criterion shall be deemed not to have been met.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

4. **The Application was completed in Polish or English. (YES/NO – REJECT THE APPLICATION)**

   (This criterion **cannot be supplemented**)

The Application must be completed in full (with the exception of the fields indicating the required language) in Polish or in English.

A criterion verified on the basis of the information provided in the Grant Application.

In accordance with the Call for Proposals' Rules and Regulations, the Application and its appendixes must be completed in Polish or English, provided that formal appendixes (e.g. the Consortium Agreement) must be drawn up in Polish.

Proper names, trade names, acronyms, and medical, scientific and technical terms may be used in Polish or English, irrespective of the language in which the Application and its appendixes have been drawn up. The presence of individual terms or names in the second language will not be regarded as a failure to meet this criterion. The Project summary must be drawn up in both Polish and English.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

5. **All mandatory fields of a formal nature have been completed. (YES/NO – REQUEST FURTHER INFORMATION / NO – REJECT THE APPLICATION)**

   (This criterion **is subject to further clarification**)

A criterion verified on the basis of the information provided in the Grant Application.

Fields of a formal nature, in particular information about the Applicant and Section

I – Proposed Intervention – may be amended in the event of an error or an obvious mistake. It is possible to amend the ORPHA code if it does not correspond to the medical condition specified in the Application and the inclusion criteria; however, it is not possible to change the content of the Application or the medical condition itself, only the code. The main focus of the check is on the consistency of the data with publicly available registers and the completeness of the tick boxes for the Applicant's declarations.

This criterion is to be supplemented only in respect of fields of a formal nature.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal assessment and being rejected.

6. **All mandatory fields relating to the content have been completed. (YES/NO – REJECT THE APPLICATION)**

   (This criterion **cannot be supplemented**)

A criterion verified on the basis of the information provided in the Grant Application.

Fields relating to the substance of the Application – specifically those concerning basic information about the Project, a description of the Applicant's activities, a description of the Project, a description of the tasks within the Project and the Project budget – must be completed with relevant information or, where justified, marked as 'not applicable' or entered as '0'.

Failure to complete the field, or completing it with content that deviates significantly from its intended purpose, results in the criterion not being met.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal evaluation

and being rejected.

7. **The maximum duration of the Project is in accordance with the Call for Proposals' Rules and Regulations. (YES/NO – REJECT THE APPLICATION)**

   (This criterion **cannot be** supplemented)

A criterion verified on the basis of the information provided in the Grant Application. In accordance with the Call for Proposals' Rules and Regulations:

- the minimum duration of the Project is 36 months (3 years),
- the maximum duration of the Project is 60 months (5 years).

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in a negative formal evaluation of the Application and its rejection.

8. **The Applicant has made provision for the monitoring of the mandatory indicators for the Call for Proposals. (YES/NO – REJECT THE APPLICATION)**

   (This criterion **cannot be supplemented**)

The verification process checks whether all mandatory indicators have been listed in the Grant Application and whether they have been planned as whole numbers greater than zero, in accordance with the requirements of the Rules and Regulations.

Indicators in the Call for Proposals:

Output indicators:

- Number of validated innovative therapeutic developed within Research

experiment,

- Number of participants included in Research experiment,
- Number of Research experiments initiated in Poland in line with regulatory requirements,
- Number of sites involved in the implementation of Research experiments under the Project,
- Number of biobanked biological material samples for the purposes of the Medical Research Agency (MRA) *(where applicable)*.

Output indicator:

- Number of publications with the results of Research experiment.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

9. **The Applicant has attached to the Application the mandatory annexes required by the Call for Proposals' Rules and Regulations. (YES/NO – REQUEST FURTHER INFORMATION / NO – REJECT THE APPLICATION/)**

   (This criterion **is subject** to further clarification)

Appendixes are checked to ensure they are complete and in the required format. This criterion is to be supplemented with regard to the following appendixes:

1) Consortium Agreement *(only for Applications submitted by a Consortium)*:
   - **drawn up in Polish;**

- signed by the Consortium Leader and the Consortium Members in accordance with their respective rules of representation;
- substantially in accordance with the template set out in Appendix 3 to the Rules and Regulations;
- the Consortium Member's (Members') Declaration(s) is/are attached *(does not apply to the Consortium Leader)*:
  - in accordance with the template set out in Appendix 3a to the Rules and Regulations;
  - submitted separately for each Consortium Member;
- documents confirming the valid authorization to represent the Consortium Leader and the Consortium Members have been attached (subject to the exception described in point 3 below);

2) Documents confirming possession of an EU Declaration of Conformity or a Certificate of Conformity for the medical *device/in vitro* diagnostic medical device used within the Project *(particularly where, in the Application, in Section I – in the 'Declarations concerning the use of Medical devices and in vitro diagnostic medical devices' field, the 'YES' box is ticked) – if applicable;*
3) **Document confirming the valid authorization to represent the Single-entity Applicant/Consortium Leader/Consortium Member** - *this applies where the signature on behalf of the entity in question is affixed by a person other than the person authorized to represent the entity (as indicated in the Application in the field 'Person authorized to make a binding decision and submit the Application'), and the authorization to represent the entity cannot be verified in publicly available registers (i.e. the National Court Register (KRS) or the register of scientific institutes of the Polish Academy of Sciences (PAN)), and in the case of public universities, a person other than the rector indicated in the information on the outcome of the election or appointment of the rector published in the university's Public Information Bulletin;*
4) **Additional formal attachments –**submitted, for example, to confirm the status of an

entity – *where applicable*.

The Consortium Agreement, statements, declarations of intent and other documents and appendixes which, in accordance with the Agency's requirements, must be signed and cannot be found in publicly accessible registers (*i.e. the National Court Register (KRS) or the register of scientific institutes of the Polish Academy of Sciences (PAN))*, must bear a qualified electronic signature (signature format compliant with the eIDAS Regulation (EU) No 910/2014; using a graphical symbol) in accordance with the authorization of the entity submitting the document. A trusted signature does not meet the requirements of a qualified signature and is not a substitute for it. These documents must be signed by:

- **the person authorized to represent the entity (as indicated in the Application in the field 'Person authorized to make a binding decision and submit the Application'), which can be verified in publicly available registers (i.e. the National Court Register (KRS) and the register of scientific institutes of the Polish Academy of Sciences (PAN)); in the case of public universities, this person is the rector named in the information regarding the outcome of the election or appointment of the rector, as published in the university's Public Information Bulletin, or**
- **the person authorized to represent the entity (as indicated in the Application in the field 'Person authorized to represent the Applicant'), for whom documents confirming their valid authorization, signed with a qualified electronic signature (in accordance with the eIDAS Regulation (EU) No 910/2014; using a graphic symbol) by a person authorized to make a binding decision and to submit the Application, or**
- **an authorized person, for whom the relevant power of attorney has been attached, signed with a qualified electronic signature (in accordance with the eIDAS Regulation (EU) No 910/2014; using a graphic symbol) by a person authorized to represent the entity.**

This criterion is to be supplemented in relation to the aforementioned appendixes.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding).

Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

10. The person in charge of the Research experiment meets the following condition:

— **The Head of Research experiment is <u>not</u> a member of the bodies of the Medical Research Agency referred to in Article 4 of the Act. (YES/NO – REJECT THE APPLICATION)**

(This criterion **<u>cannot</u> be supplemented**)

This criterion is assessed on the basis of the content of the Grant Application and the composition of the Medical Research Agency's governing bodies as at the date of submission of the Grant Application.

In accordance with the Rules and Regulations, if a person who is a member of the bodies of the Medical Research Agency referred to in Article 4 of the Act (the Agency's Council, the President of the Agency) is listed in the Grant Application as the Head of Research experiment the Applicant does not meet the formal criterion in question.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

11. **Head of Research Experiment:**

    — **holds a medical licence and has completed a specialization, and**

    — **holds a PhD and**

    — **is nominated as the Head of Research experiment in no more than two applications in the Call for Proposals. (YES/NO – REQUEST FURTHER INFORMATION / NO – REJECT THE APPLICATION)**

    (This criterion **is subject to further details**)

Criterion verified on the basis of the content of the Grant Application and the information available in the Central Register of Doctors: https://rejestr.nil.org.pl/.

The Head of Research experiment must hold at least a doctoral degree in medical sciences and health sciences, including a degree obtained in accordance with previously applicable regulations in the field of medical sciences, or an equivalent degree obtained abroad; and, within the meaning of Article 23(1) of the Act of 5 December 1996 on the professions of doctor and dentist, the qualifications of a doctor specializing in a field of medicine that is particularly relevant to the nature or conduct of the experiment, and appropriately high professional and research qualifications.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

12. **The amount of funding applied for is less than or equal to PLN 12 million. (YES/NO – REJECT THE APPLICATION)**

    (This criterion **cannot be supplemented**)

A criterion verified on the date the Grant Application is submitted.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

13. **The entity submitting the Application via the ICT system – whether a single-entity Applicant, a Consortium Leader or a Consortium Member – has submitted no more than four Applications in the Call for Proposals. (YES/NO – REJECT THE APPLICATION)**

    (This criterion **cannot be** supplemented.)

A single entity (regardless of the role it plays in the relevant Application, i.e.: a Single-entity Applicant, a Consortium Leader or a Consortium Member may submit a maximum of four Applications under the Call for Proposals.

Where a Single-entity Applicant, a Consortium Leader or a Consortium Member has branches which are entered in the National Court Register under the same KRS number, those branches shall be deemed to be the same Single-entity Applicant, Consortium Leader or Consortium Member.

If more than four Applications are submitted involving the same entity – regardless of the role it plays – all Applications involving that entity will be deemed not to meet this formal criterion.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

14. The Project relates to a Research experiment. (**YES/NO – REQUEST FURTHER INFORMATION / NO – REJECT THE APPLICATION)**

(This criterion **is subject** to amendment.)

In accordance with the Rules and Regulations, the Application must relate to the conduct of a Research experiment. This criterion is assessed in accordance with the Call for Proposals' Rules and Regulations, and the Act of 5 December 1996 on the professions of doctor and dentist.

The criterion will be assessed on the basis of the Application as a whole, with particular regard to Section *II.B.* of the Application. *Project – substantive part / II.B. Project – the main body*, *including*: *Identification data of the Research experiment*, *section I – proposed intervention*.

Under this criterion, it is assessed whether the research experiment Project:

- complies with the definition of a 'Research experiment' as set out in the Act of 5 December 1996 on the professions of doctor and dentist;
- meets all the conditions set out in the definition of a 'Research Experiment' as set out in the Glossary of Terms and the other provisions of the Call for Proposals' Rules and Regulations.

Examples of studies that do not meet the criterion:

- Non-interventional study;
- Observational study;
- Clinical Trial of a Medicinal product (including a low-intervention Clinical Trial);
- Clinical Trial of a Medical device;
- Performance evaluation of an in vitro diagnostic medical device;
- A Clinical Trial in which the Medicinal product is administered under a hospital exemption (HE).

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding).

Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

15. **The planned Research experiment has at least two arms. (YES/NO – REJECT THE APPLICATION/NOT APPLICABLE – THE APPLICATION RELATES TO RESEARCH EXPERIMENT PARTICIPANTS INVOLVING A RARE DISEASE)**

    (This criterion **cannot be** amended.)

Call for proposals ABM/2026/3 is dedicated to Research experiments that include a control or comparison group.

The above requirement does not apply to Projects in which the **entire** population of participants included in the study consists solely of Research experiment participants with a rare disease* (i.e. having a Rare disease is a criterion for inclusion in the study).

* Verification of the status of a Rare disease is based on the data available

in the Orphanet database (www.orpha.net) as at the date of submission of the Application. **The Applicant is required** to provide the correct ORPHAcode in the Application.

Note: A condition is not recognized as a Rare disease if the ORPHAcode description includes a note stating that it is not a Rare disease in Europe.

The criterion will be assessed on the basis of the Application as a whole.

Mandatory criterion (fulfilment of this criterion is essential in order to be eligible for funding). Failure to meet this criterion will result in the Application receiving a negative formal evaluation and being rejected.

4.2 Substantive Evaluation Procedure

The criteria for the substantive evaluation cannot be supplemented.

Every Application is subject to a substantive evaluation, provided it has passed the formal evaluation stage and has not been withdrawn by the Applicant.

The substantive assessment covers the following criteria:

- **Statutory criteria**

  Statutory criteria are mandatory. An Application must be assessed as at least 'good' under each statutory criterion (in accordance with the scoring ranges set out in Appendixes 6 and 7 to the Rules and Regulations) in order to receive funding. Statutory criteria are evaluative in nature.

- **Bonus criteria**

  The bonus criteria are not mandatory. Failure to meet a particular bonus criterion does not mean that the Application will be rejected. If an Application meets a bonus criterion, it is awarded the number of points specified for that criterion.

The substantive evaluation is carried out by experts.

The substantive evaluation carried out by AAP will consist of two stages:

1. **Stage I of the substantive evaluation** (of Applications meeting the formal requirements) carried out by at least two experts, in accordance with the criteria set out in Appendix 6, which constitutes a proposed evaluation to be verified by a panel of experts.

   Appendix 6 sets out in detail the criteria for selecting Projects (statutory criteria and bonus criteria), together with an explanation of their significance.

   Each assessor records their assessment of a given criterion, together with any comments, in the relevant sections of the Substantive Evaluation Form.

2. **Stage II of the substantive evaluation**, carried out during the expert panel meeting, involves awarding points from the pool allocated for a given criterion in the form of

whole numbers (with no fractional values), in accordance with the criteria set out in Appendix 7.

Experts are appointed to the Application Evaluation Panel. The AAP may also include specialists in the fields of financial analysis and statistics.

The AAP shall draw up a written summary of the assessments of individual Applications (including scores), containing references to all the criteria subject to assessment (statutory and bonus criteria) in accordance with Appendix 7.

A ranking list is drawn up based on the scores achieved in the second stage of the substantive evaluation. A place on the ranking list is determined by the number of points awarded by the panel in accordance with the statutory and bonus criteria. Applications are ranked according to the scores they have received: from highest to lowest, taking into account the rules set out in subsection 5.2, *'Ranking List'*.

An Application may be awarded a maximum of **60 points** in total, of which:

- a maximum of **54 points** for statutory criteria;
- a maximum of **6 points** for bonus criteria.

4.3 Stage of consideration of comments on the budget

Applications that are designated as recommended for funding in the Call for Proposals, and for which experts have highlighted comments requiring changes to the budget, may proceed to the stage of incorporating these comments into the budget (hereinafter: budget update). The scope of this update is set out in Appendix 8 to the Rules and Regulations.

Information regarding the outcome of the Project budget update is provided to Applicants together with a letter notifying them of the outcome of the Call for Proposals via e-Delivery to the electronic service address specified in the Application or, if no such address is specified in the Application, to the address corresponding to the Applicant's tax identification number (NIP) (and, in the absence of an address for electronic service, it is sent via the public hybrid service) prior to the commencement of any contract signing procedure.

The Applicant is required to implement all the guidelines and changes contained in the budget update (where applicable).

The inclusion in the Application of all the guidelines and amendments set out in the budget update (where applicable) is a prerequisite for receiving funding and commencing the process of signing the Project Funding Agreement; however, it does not in itself constitute the finalization of the process of signing the Funding Agreement.

5. Outcome of the Call

5.1. Conditions for obtaining recommendations for co-financing

An Application may be recommended for funding if it meets all of the following conditions:

- will be assessed positively in formal terms;
- **as part of the second stage of the substantive evaluation, it will be assessed under each statutory criterion as at least 'good'** – in accordance with the assessment (scoring ranges) for the individual criteria set out in Appendix 7 to the Call for Proposals' Rules and Regulations – Panel Evaluation Sheets;
- will be amended in accordance with the recommendations set out in the budget update (where applicable – the Application should only be amended in accordance with the recommendations contained in the budget update at the stage of signing the Co-financing Agreement; fulfilment of this condition will then enable the Project Co-financing Agreement to be signed) and
- the amount of funding recommended falls within the allocation available for the Call for Proposals, taking into account the position on the ranking list of Applications, which is ordered according to the scores awarded.

Irrespective of whether the Applicant meets formal criterion No. 10 as set out in subsection 4.1.1, Formal Evaluation Criteria, if, following the submission of Applications, during the Call for proposals procedure and up to the point of concluding the Co-financing Agreement, a person who is a member of the Agency's bodies referred to in Article 4 of the Act (the Agency's Council, the Agency's President), is named in the Grant Application as the Head of Research experiment (regardless of whether this is due to an appointment to that role or to amendments to the Application), the Applicant is obliged to immediately withdraw the Application from the Call for Proposals.

The above applies to every stage of the Call for proposals procedure, from the submission of the Application right through to the conclusion of the Co-financing Agreement. The

Applicant is required to withdraw their Application from the Call for Proposals immediately upon the fulfilment of the above condition.

Should the Applicant fail to fulfil this obligation and the Agency become aware of the above situation, the Agency will request the Applicant to provide an explanation within 7 days of receiving the request. Following an analysis of the detailed explanations provided and having established the existence of the aforementioned links, the President of the Agency shall notify the Applicant that the Grant Application has been left unexamined or, where no such links are found, that the assessment of the Application will proceed. Should the Applicant fail to comply with the above request by the specified deadline, the Agency will leave the Application unexamined.

5.2 Ranking list

Once the Application Evaluation Team has completed its work, a ranking list is drawn up in accordance with Article 19 of the Act, containing the following information:

- the name of the Applicant (in the case of Projects carried out by a Consortium, the details of the Consortium Leader and the Consortium Members are published);
- the number of points awarded to the Application;
- Project title,
- information on whether the Project is recommended for funding;
- the amount of public funding allocated.

A Project's position on the ranking list is determined by the total number of points awarded by the experts during the second stage of the substantive evaluation, based on the substantive criteria. **Applications are ranked according to the scores they have achieved.** In the event that two or more Applications receive the same number of points, the Applications that have met all the substantive criteria to at least a 'good' standard are placed first in the ranking list, followed by those that have not met this condition. The order of Applications within each of these categories is then determined by the higher score awarded under the statutory criterion: *Applicability of the Project results in the healthcare*

system. If the number of points awarded under the above criterion is the same for two or more Applications under consideration, the order on the ranking list shall be determined by the higher score awarded under the statutory criterion: *Expected economic effects*.

If the Applications concerned receive the same number of points under both tie-breaking criteria, they shall be placed on the ranking list in ascending order by Application number.

Applicants are notified of the results of the Call for Proposals by electronic letter via e-Delivery to the address for electronic service specified in the Application or, if no such address is specified in the Application, to the address corresponding to the Applicant's tax identification number (NIP); and where no address for electronic service is provided, they are notified via the public hybrid service).

5.3 Complaint

Applicants whose Project has not been recommended for funding as a result of the Call for Proposals are entitled to lodge an appeal with the President. An appeal must be lodged within 14 days of the date of serving the letter setting out the results of the Call for Proposals. The objection must be submitted in writing.

The President may either accept or reject the protest within 30 days of receiving it. In order to consider the objection, the President may refer the Application to which the objection relates to the appeals committee for reassessment. The statement template is attached as Appendix 9 to the Rules and Regulations.

Following the consideration of the appeals, a ranking list of Applications is drawn up after the appeal procedure. A position on the ranking list is determined by the total number of points awarded by the experts on the basis of the substantive criteria, following the consideration of any appeals. Applications on the ranking list are ranked according to the scores awarded following the consideration of appeals; where Applications have the same number of points, the provisions of subsection 5.2 of the Rules and Regulations shall apply mutatis mutandis. The President shall take the protest into account if:

- it has been assessed as at least 'good' under each statutory criterion, and

- the number of points awarded to the Application following the consideration of the appeal is greater than or equal to the number of points awarded to the last Application recommended for funding on the ranking list referred to in section 5.2 of the Rules and Regulations, and
- the amount requested falls within the financial reserve established pursuant to Article 19(11) of the Act.

The outcome of the President's consideration of a protest – whether it is upheld or rejected – is not an administrative decision within the meaning of the provisions of the Act of 14 June 1960 – Code of Administrative Procedure (hereinafter: CAP). The Act introduces a separate and specific procedure for assessing protests. The provisions of the Code of Administrative Procedure apply only to the matters regulated in Article 19(13) of the Act. The dissatisfied party may challenge the President's rejection of the protest on the basis of the relevant legal provisions.

Note:

Additional information submitted as part of the appeal procedure but not disclosed in the originally submitted Application may not form the basis for changing the outcome of the assessment of the Application at the appeal stage. The appeal process is not intended to provide additional information whose absence led to a reduction in the Application's score, but rather to demonstrate that the experts assessing the Application misinterpreted the information provided in the Application or overlooked it entirely.

6. Final provisions

Submission of the Application constitutes acknowledgement and acceptance of the contents of the Rules and Regulations and the documents attached thereto.

At the same time, the Agency reserves the right, amongst other things, to:

- introduce amendments to the Rules and Regulations or to any document setting out the terms and conditions of the Call for Proposals to which the Rules refer. In such cases, the amendments shall take effect from the date specified in the notice regarding those amendments, published on the Agency's website. The changes must not result in unequal treatment of Applicants, unless they stem from generally applicable law,
- the cancellation of the Call for Proposals in accordance with Article 19(3) of the Act, in particular in the event of significant changes to the law affecting the conditions under which the Call for Proposals is conducted, the occurrence of events constituting force majeure, or other cases justified by a relevant decision of the President,
- to refrain from concluding the Co-financing Agreement until the concerns have been clarified, or to refuse to conclude it should MRA have reasonable grounds to doubt the Applicant's ability to spend public funds correctly, including in accordance with the objectives of the Call for Proposals and the Project,
- failure to sign the Co-financing Agreement in accordance with the provisions set out in the Call for Proposals' Rules and Regulations, **which may result in the withdrawal of the recommendation for the Project to receive funding, an adjustment to the ranking list and the funding not being awarded.**

The transfer of funds is conditional upon the signing of the Co-financing Agreement. The Applicant undertakes to enter into a Co-financing Agreement within 30 days of the date on which they are notified of the results of the Call for Proposals regarding the recommendation of the Project for funding. **The Agency reserves the right to state that failure to meet the above-mentioned deadline may result in the withdrawal of the**

recommendation for the Project to receive funding, an adjustment to the ranking list and the funding not being awarded.

In the event of withdrawal from the conclusion of a Co-financing Agreement, the Agency may decide either to recommend the next Project in the ranking list of positively assessed Applications for funding, or to allocate the released funds to increase the allocation reserve set aside for financing Projects recommended for funding as a result of the appeal procedure.

All appendixes to the Agreement must be drawn up in accordance with the following conditions:

- must be saved in .pdf format and bear a qualified electronic signature (in accordance with the eIDAS Regulation (EU) No 910/2014; using a graphic symbol) of the authorized person or
- their conformity must be certified electronically by a notary in accordance with Article 97(2) of the Act of 14 February 1991 – the Notarial Law.

The Appendixes attached to these Rules and Regulations form an integral part thereof.

1) Application Form Template:
    a) Application Form – Polish version;
    b) Application Form – English version.
2) Project Co-financing Agreement Template;
    a) Co-financing Agreement for a Single-Entity Beneficiary - template;
    b) Co-financing Agreement for a Multi-Entity Beneficiary - template.
3) Consortium Agreement Template.
4) Template of the Agreement on the collection, storage, safeguarding, transfer and provision of Material, including Biological material, for the purposes of future

scientific research or research and development, and Template of the Agreement on the processing of personal data:

a) Template of the Agreement on the collection, storage, safeguarding, transfer and provision of access to Material, including Biological material, for the purposes of future scientific research or research and development – between MRA and the Beneficiary;

b) Template of the Agreement on the collection, storage, safeguarding, transfer and provision of access to Material, including Biological material, for the purposes of future scientific or research and development studies – between the Beneficiary and the biobank;

c) Template of the Agreement on the collection, storage, safeguarding, transfer and provision of access to Material, including Biological material, for the purposes of future scientific or research and development studies – between the Beneficiary and the Consortium Member's biobank;

d) Personal Data Processing Agreement Template.

5) A list of the most common costs.

6) Substantive Evaluation Cart Template.

7) Panel Evaluation Cart Template.

8) Project Budget Update Template.

9) A template for an appeal against the results of the Call for Proposals.

10) Statement on State Aid Template.

11) Guidelines for auditors of Projects funded by the Medical Research Agency.