

## **Regulations of Co-operation between the Medical Research Agency and the external Experts**

### **§ 1**

#### **General Provisions**

1. The Regulations of Co-operation between the Medical Research Agency and the external Experts, hereinafter referred to as "Regulations of the MRA" specify:
  - 1) requirements for candidates for Experts
  - 2) the mode of selecting candidates for Experts and their entry into the Database as well as the mode of deleting the data of a candidate for Expert from the Database;
  - 3) the way of controlling the personal data of the candidates for Experts and Experts;
  - 4) the principles of remuneration of Experts and settlement of travel and accommodation costs;
  - 5) ethical principles that Experts must comply with.
2. External experts, hereinafter referred to as "the Experts", are persons both from the Republic of Poland and from abroad, carrying out substantive assessment of Project Co-Financing Applications submitted in the calls for proposals conducted by the MRA. The Experts may also engage in other activities, such as: assessment of Project Co-Financing Applications following an appeal, substantive assessment of Interim/Final Project Reports, substantive assessment of amendments to Project Co-financing Applications, Project inspections or performing other Orders.
3. Formal requirements for candidates for Experts are set out in Art. 18 (2) of the Act of 21st February 2019 on Medical Research Agency (Polish Journal of Laws 2022, item 451).
4. The terms or abbreviations used in the Regulations shall have the following meaning:
  - 1) **MRA, the Agency** - the Medical Research Agency;
  - 2) **The Database of Candidates for Experts, the Database** - a database of persons who have applied for inclusion in the Database and have met the formal requirements for candidates for Experts;
  - 3) **The Beneficiaries** - entities that have received co-financing under the Agency's calls for proposals;



- 4) **The Expert** - a person entered into the Database of Candidates for Experts with whom the MRA has concluded a framework contract;
- 5) **The President** - the President of the MRA;
- 6) **Reports** - partial, interim or final Reports submitted by the Beneficiaries;
- 7) **MRA's ICT system** - the system referred to in Article 21 of the Act, by means of which the call for proposals and the assessment of Applications for Co-Financing and the assessment of Reports submitted by the Beneficiaries are conducted;
- 8) **The Act** - the Act of 21st February 2019 on the Medical Research Agency;
- 9) **Application** - application for entry in the Database of Candidates for Experts of the Medical Research Agency constituting Appendix 1 to the Regulations of co-operation between the Medical Research Agency and the external Experts;
- 10) **Application for Co-Financing** - application for implementation and co-financing of a Project;
- 11) **The Order** - the order for expert activities in accordance with the scope defined in Art. 18 (1) or (1a) of the Act.

## § 2

### Requirements for candidates for Experts

1. A candidate for Expert may be a person that:
  - 1) enjoys full civil rights;
  - 2) has full legal capacity;
  - 3) has not been convicted of an intentional crime or deliberate fiscal offence by a final judgement;
  - 4) holds:
    - a) at least higher education in the field of medical and health sciences and documented professional experience of at least 5 years in clinical trials; or
    - b) at least a Ph.D. degree in the field of medical and health sciences (or a higher degree/ title); or
    - c) at least higher education degree (has at least the M.A., or M.Sc. degree, or equivalent) in the field of science and natural sciences or engineering and technical sciences or social sciences, in particular in the field of economy and finance and juridical sciences; and
    - d) at least 5 years of documented professional experience in the area of research, economy or finance.



2. An applicant for a candidate for Expert shall submit a declaration on the fulfilment of prerequisites referred to in paragraph 1. Such declaration shall constitute Appendix 2 to the Regulations. The declaration is submitted under pain of criminal prosecution for perjury.
3. The candidate for Expert shall inform the MRA immediately of any circumstances as a result of which the prerequisites referred to in paragraph 1 are no longer met.

### § 3

#### **The mode of selection of candidates for Experts**

1. The MRA shall create the Database of Candidates for Experts.
2. The application of a candidate to the Database is made on the basis of the Application, the specimen of which is given in Appendix 1 to the Regulations, sent to the MRA via the ICT system or via e-mail in the form of a document signed with a qualified electronic signature to the address: [eksperci@abm.gov.pl](mailto:eksperci@abm.gov.pl), or in a paper form by registered mail to the address: Medical Research Agency, ul. Chmielna 69, 00-0801 Warsaw.
3. The recruitment of candidates for Experts is a continuous process.
4. Submitting an Application for inclusion in the Database of Candidates for Experts is not tantamount to obtaining the status of a candidate for Expert. The status of a candidate for Expert is granted to a person whose Application has been successfully processed.
5. The evaluation of applications for candidates for the Experts is carried out by the competent MRA staff.
6. It is envisaged that Applications for inclusion in the Database of Candidates for Experts may be supplemented on the basis of a notification from a MRA employee submitted by electronic means.
7. Applicants for candidates for Expert status shall be informed about the result of their application process by electronic means and, if the Application is rejected, also about the reasons for not being included in the Database.
8. Applicants for candidates for Expert status whose Applications for inclusion in the Database are rejected have no possibility to appeal against the outcome of the verification of the Application. However, they may reapply for inclusion in the Database if they are able to remove the reasons for rejection of the previously submitted Application.
9. Obtaining the candidate for Expert status does not imply any obligation on the part of the MRA to enter into an agreement with the candidate to perform any tasks.
10. Entering candidates for Experts into the Database is not tantamount to appointing them to the Application Evaluation Team.



11. In compliance with Art. 10 (2) of the Act, the function of a member of the MRA Board cannot be combined with the function of the Expert.
12. Candidates for Experts entered into the Database shall update their data being the subject of the Application for entry into the Database on an ongoing basis.
13. The Expert shall perform the activities referred to in § 1 (2) on the basis of a framework agreement on co-operation with an Expert, upon receipt of an Order sent by an authorised MRA staff member. The order shall be placed via an ICT system or electronic mail.
14. Together with signing the agreement referred to in paragraph 13, the Expert shall submit to the MRA a completed and signed Form, a template of which has been attached as Appendix 5 to the Regulations, if applicable<sup>1</sup>.

#### § 4

##### **Principles concerning Experts' work**

1. Appointment of the Application Evaluation Team takes place in accordance with the principles set out in Art. 18 of the Act.
2. The detailed rules for awarding Orders to Experts shall be the subject of a framework agreement for cooperation with an Expert and the detailed scope of the Order shall be defined in the Order Form, a template of which is attached as Appendix 3 to the Regulations.
3. The Agency shall furnish the Experts with all documentation necessary for the performance of the Order.
4. The Experts are obliged to read the received documentation and perform the Order according to the assigned scope and within the applicable deadline.
5. The names and residence addresses of members of the Application Evaluation Team appointed by the ordinance of the President shall be public and may be made publicly available.
6. The details referred to in paragraph 5 shall not be made available in a way that would make it possible to identify individual assessors who reviewed a particular Application for Co-Financing.

#### § 5

##### **Experts' personal data**

1. The controller of the Experts' personal data is the MRA.

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<sup>1</sup> Only applies to persons who are not self-employed.



2. The processing of personal data is performed in compliance with Art. 6 (1) (b) and Art. 6 (1) (c) in relation with the Act as well as Art. 6 (1) (e) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (the GDPR).
3. The processing of personal data is carried out with the view to conducting cooperation with the MRA on the principles set out in these Regulations and in the content of other regulations, specified in the framework agreement for cooperation with an Expert or in the ordinance of the President of the MRA, in particular with the view to:
  - 1) performing a substantive assessment of the Project Co-Financing Application, along with a detailed justification of the awarded score;
  - 2) performing a substantive assessment of the Project Co-Financing Application following an appeal;
  - 3) performing a substantive assessment of the Interim/Final Report;
  - 4) performing a substantive assessment of amendments to the Project Co-Financing Application;
  - 5) participating in remote Project inspections;
  - 6) participating in person in on-site inspections at the premises of the Project owner(s);
  - 7) making payments of remuneration for the assessments performed;
  - 8) participating in meetings of Expert Teams;
  - 9) performing other Orders;
  - 10) reimbursing travel costs in accordance with § 18 (13) of the Act.
4. The Expert's data may be made available only to entities entitled to obtain personal data on the basis of legal provisions, entities which operate the Controller's ICT systems and provide ICT tools (e.g. hosting services, cloud services, record destruction) or entities providing mail services and entities cooperating with the MRA in the performance of tasks, specified in documents listed in paragraph 3.
5. The provision of personal data is voluntary, but necessary for the cooperation with MRA and the payment of due remuneration or reimbursement of incurred costs.
6. The Expert's personal data shall not be subject to automated decision-making, including profiling.
7. The data shall be stored for the period of:
  - 1) co-operation with the Expert and for 3 years from the notification of the deletion of the Expert from the Database;
  - 2) fulfilment of obligations arising from the legal provisions and related to cooperation, in particular from the Accounting Act;



- 3) conducting settlements under sections 1 and 2;
- 4) as set forth in the Office Instruction and Subject File Index.
8. The Expert being the data subject shall have the right to:
  - 1) request access to his/ her data, rectify or delete them, or limit their processing;
  - 2) lodge a complaint with the supervisory authority (the President of the Personal Data Protection Office, ul. Stawki 2 00-193 Warsaw) in compliance with the principles specified in the GDPR.
9. The Expert shall have the right to object to the processing of personal data.
10. In matters related to personal data protection, the Experts shall contact the MRA Data Protection Officer at the e-mail address: [iod@abm.gov.pl](mailto:iod@abm.gov.pl).
11. The Expert's personal data will not be transferred to any third country/ international organisation, unless the Controller is required to do so by law.

## § 6

### **Experts' remuneration and principles of cost reimbursement**

1. The amount of remuneration is specified each time in the Order.
2. The remuneration rates for performing an Order are specified in Appendix 7 to the Regulations.
3. The Experts residing outside the locality in which the meeting of the Application Evaluation Team is held shall be entitled to reimbursement of travel and accommodation costs in accordance with Art. 18 (13) of the Act.
4. The procedure and terms of reimbursement of travel and accommodation costs are specified in Appendix 8 to the Regulations.
5. A template request for reimbursement of travel and accommodation costs is attached as Appendix 9 to the Regulations.

## § 7

### **Ethical rules**

1. The Experts of the MRA are obliged to care for the good name of the MRA, to perform their duties in a timely manner and according to the highest standards of diligence and expertise.
2. The Experts shall be professional, independent, impartial and reliable in their activities.
3. The Experts are required to comply with the principles set out in the current version of the Code of Ethics of the Medical Research Agency, which includes elements of anti-corruption policies.



4. An Expert shall keep confidential all information provided to him/ her by the Ordering Party in connection with the performance of the subject matter of the framework agreement.
5. Prior to undertaking the first Order, the Expert shall make a declaration of familiarity with the Code of Ethics of the Medical Research Agency including elements of anti-corruption policies; a template Declaration is attached as Appendix 6 to these Regulations.
6. An Expert performing activities referred to in § 1 (2) may not remain with the entity contemplated in the Order:
  - 1) in a professional relationship or other form of cooperation while performing an Order and for 3 years beforehand;
  - 2) in such a legal or factual relationship that the results of performing the Order can affect his/ her rights or obligations.
7. Prior to commencing Order performance, the Expert shall make a relevant Declaration of Impartiality and Confidentiality (hereinafter referred to as "the Declaration") . Such Declaration is made under criminal liability. The template of the Declaration has been attached as Appendix 4 to these Regulations.

## § 8

### **Mode of deleting the candidate for Expert's data from the Database**

1. The rationale for removing a candidate for an Expert from the Database is:
  - 1) the Expert's submission of his/her resignation from cooperation with MRA;
  - 2) failure to submit the required declarations in the course of cooperation with the MRA or making false declarations;
  - 3) failure to meet any of the requirements indicated in § 1-2;
  - 4) non-fulfilment of the tasks specified in § 4;
  - 5) non-compliance with ethical principles referred to in § 7.
2. The President may also delete an Expert from the Database for other legitimate reasons than those referred to in paragraph 1.
3. The Expert shall be notified of having been deleted from the Expert Database at least by electronic means.
4. An expert who has been deleted from the Database as a result of a breach of ethical principles may not reapply for inclusion in the Database for a period of three consecutive years from the date on which he/she was informed of this fact.

The following Appendices shall constitute an integral part of the Regulations:



1. The template of the Application for entry in the Database of Candidates for Experts of the MRA.
2. The template of a declaration of a candidate for an Expert of the MRA.
3. Order template.
4. The template of the Declaration on Impartiality and Confidentiality.
5. The Expert data form for settlement purposes.
6. Template declaration of familiarity with the MRA Code of Ethics including elements of anti-corruption policies.
7. Expert remuneration table.
8. The procedure and terms of reimbursement of travel and accommodation costs.
9. Request for reimbursement of travel and accommodation costs.