

Appendix 1 to the Regulations of co-operation between the Medical Research Agency and the external Experts

The Application for entry in the Database of Candidates for Experts of the Medical Research Agency

I, the undersigned, hereby apply to be included in the *Database of Candidates for Experts* (hereinafter referred to as: the Database)

1. PERSONAL DATA	
Name(s) and surname	
Personal Identification Number (PESEL) ¹	
Residence address	
Correspondence address ²	
Tax ID no. ³	
Contact phone no.	
E-mail	
Current workplace (in the case of being employed in more than one place of work, please list all such places)	

2. EDUCATION (if necessary, include more copies of the headings specified below)	
Name of completed	

¹ To be completed by persons not conducting business activity.

² Please complete if different from the residence address.

³ To be completed by persons conducting business activity.



higher education establishment	
Year of graduation from the higher education establishment	
Major/ specialisation	
Obtained title/degree/type of diploma	
Professional licence number - if applicable	

3. SUPPLEMENTARY EDUCATION
(postgraduate studies, Ph.D. studies, etc.
– if necessary, include more copies of the headings specified below)

Name of the establishment organising education	
Year of graduation	
Major/ specialisation	
Obtained title/degree/type of diploma	

4. PROFESSIONAL EXPERIENCE
(if necessary, include more copies of the headings specified below)

Employment period (from – to)	
Place of work	



Town / City	
Position held	
Scope of performed tasks and activities	

5. ADDITIONAL INFORMATION

Experience in reviewing/assessment of clinical research Projects of medicinal products/medical devices	
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Other experience, qualifications, skills or practice justifying the application for inclusion in the Database with the indication of the field/aspect concerned (e.g. courses, training, academic achievements, publications, organisational operations, expert opinions etc.)	
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I hereby confirm the authenticity of the data contained in the form by my handwritten signature

Town/city: date:

.....

Legible signature of the Candidate for Expert

In compliance with Art. 13 of the Regulation (EU) No 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) (OJ of the EU No. L. 119 of 2016) I hereby inform that:



1. The Controller of your personal data is the Medical Research Agency, at ul. Chmielna 69, 00-801 Warsaw.
2. The Controller has appointed a Data Protection Officer whom you can contact at iod@abm.gov.pl;
3. Your personal data shall be processed with the view to conducting a recruitment process for candidates for Experts of the Medical Research Agency.

If you are entered in the list of candidates for Experts, the processing of personal data may be carried out with the view to conducting cooperation with the MRA on the principles set out in these Regulations and in other regulations specified in the framework agreement for cooperation with an Expert or in the ordinances of the President of the MRA, in particular with the view to:

- a) performing a substantive assessment of the Project Co-Financing Application, along with a detailed justification of the awarded score;
 - b) performing a substantive assessment of the Project Co-Financing Application following an appeal;
 - c) performing a substantive assessment of the Interim/Final Report;
 - d) performing a substantive assessment of amendments to the Project Co-Financing Application;
 - e) participating in remote Project inspections;
 - f) participating in person in on-site inspections at the premises of the Project owner(s);
 - g) making payments of remuneration for the assessments performed;
 - h) participating in meetings of the Application Evaluation Team;
 - i) performing other Orders;
 - j) reimbursing travel costs in accordance with § 18 (13) of the Act.
4. 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).
 5. Your personal data shall be stored by the Controller for the period necessary to achieve the above-mentioned purposes, i.e. until the end of the recruitment process for candidates for Experts of the Medical Research Agency, and if you are entered in the list of candidates for Experts, the personal data may 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.
6. Your personal 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 listed in paragraph 5.
 7. Your personal data shall not be subject to automated decision-making, including profiling.
 8. You have the right to demand from the Controller the access to personal data, the right to rectify them, erase them or limit their processing and the right to data portability.
 9. You have the right to object to the processing of data.
 10. You have the right to lodge a complaint with the supervisory authority - the President of the Office for Personal Data Protection.
 11. The provision of your data is voluntary, however it is necessary for conducting a recruitment procedure for candidates for Experts of the Medical Research Agency. If you are entered in the list of candidates for Experts, the data will be necessary for the cooperation with MRA and the payment of due remuneration or reimbursement of incurred costs.
 12. Your personal data will not be provided to a third country/ international organisation, unless the Controller is required to do so by law.

.....

Legible signature of the candidate for Expert



Appendix 2 to the Regulations of co-operation between the Medical Research Agency and the external Experts

.....

First and surname

DECLARATION OF A CANDIDATE FOR EXPERT OF THE MEDICAL RESEARCH AGENCY

I, the undersigned, (first name and surname) hereby declare that:

- 1) I enjoy full civil rights;
- 2) I have full legal capacity;
- 3) I have not been convicted of an intentional crime or deliberate fiscal offence by a final judgement;
- 4) I hold:
 - 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 (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.

Furthermore, I undertake to inform the Agency of changes and circumstances affecting the fulfilment of the criteria set out in the call for candidates for Experts. I hereby confirm that I have become acquainted with the Regulations of Co-operation between the Medical Research Agency and the external Experts, I accept their provisions and I shall comply with them.

I hereby represent that the information contained in this Declaration is true.

.....

Place and date

.....

Legible signature of the Candidate for Expert



Appendix 3 to the Regulations of co-operation between the Medical Research Agency and the external Experts
Warsaw,

Letter no.

Order no.

on the basis of the Agreement no. of

The Medical Research Agency hereby orders the performance of:

a substantive assessment of the Project Co-Financing Application, along with a detailed justification of the awarded score	
a substantive assessment of the Project Co-Financing Application following an appeal	
a substantive assessment of the Interim/Final Report	
a substantive assessment of amendments to the Project Co-Financing Application	
participation in remote Project inspections	
participation in person in on-site inspections at the premises of the Project owner(s)	
other: ⁴	

Project No.	Project title
Amount of gross remuneration In words:

Time limit for Order performance	DD/MM/YYYY
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Remuneration amount: PLN gross (in words)

Any correspondence related to Order performance must be sent to the e-mail address: or ePUAP box address (subject to detailed rules concerning the transfer of documentation resulting from the performance of the subject matter of the Order indicated in the Agreement). The competent contact person of the Ordering Party with regards to Order performance shall be: Phone no. e-mail address:

SIGNATURE OF THE ORDERING PARTY

.....

⁴ The order for expert activities in accordance with the scope defined in Art. 18 (1) or (1a) of the Act.
Medical Research Agency, ul. Chmielna 69, 00-801 Warsaw
e-mail: kancelaria@abm.gov.pl
NIP: 5252783949 REGON (Statistical Number): 382836515



Appendix 4 to the Regulations of co-operation between the Medical Research Agency and the external Experts

DECLARATION ON IMPARTIALITY AND CONFIDENTIALITY

/ A TEMPLATE /

EXPERT (FIRST NAME AND SURNAME):

APPLICATION/PROJECT NO.:.....

APPLICATION/PROJECT TITLE:.....

APPLICANT/BENEFICIARY/CONTRACTOR:.....

I hereby declare that:

there are no circumstances that may give rise to reasonable doubts as to my impartiality with regards to the aforementioned Applicant/Beneficiary/Contractor, and also:

- 1) I have not participated personally in the preparation of the above Application/Project;
- 2) I do not have a personal relationship with the Applicant/Beneficiary/Contractor that could raise doubts as to my impartiality;
- 3) I declare the following with respect to the Applicant/Beneficiary/Contractor:
 - a) I'm not married to him/her, or in a relation of kinship and affinity to second degree,
 - b) I have not been related to him/her due to adoption, custody or guardianship;
- 4) I am not in a legal or factual relationship with the Applicant/Beneficiary/Contractor due to which the results of the opinion or assessment could affect his/ her rights or obligations;
- 5) I have not been in a professional relationship or other form of cooperation with the Applicant/Beneficiary/Contractor during the period of work within the team and I had not been in such a relationship or other form of co-operation for 3 years preceding the submission of the aforementioned Application or the assessment/while issuing the opinion or performing the assessment and within 3 years preceding the issuance of the opinion or the performance of the assessment, including:
 - a) I am not in an employment relationship with the Applicant/Beneficiary/Contractor and I had not been in such a relationship for the three years preceding the date of this declaration,
 - b) I do not provide, and had not provided for three years preceding the date of this declaration, services under civil law relationships to the Applicant/Beneficiary/Contractor that may raise doubts about my impartiality,



- c) I am not and had not been a member of the management or supervisory bodies of the Applicant/Beneficiary/Contractor during the three years preceding the date of this declaration,
- d) I am not and I had not been a partner, shareholder or stockholder of the Applicant/Beneficiary/Contractor during three years preceding the date of this declaration.

Furthermore **I represent that:**

- 1) I undertake to treat any information obtained in connection with Order performance as confidential information and I shall keep it secret, and I also undertake not to disclose it to any third parties;
- 2) I undertake to use any information obtained in connection with Order performance only for the purposes related to Order performance;
- 3) I undertake not to copy, reproduce, publish or distribute, in whole or in part, any information related to Order performance, except for cases where these activities are performed for the purposes related to Order performance.

I am aware of criminal liability for making any false statements arising from Art. 233 § 1 of the Penal Code Act of 6 June 1997⁵.

..... date

(town/city)

.....

(legible signature of the Expert)

⁵ Whoever, in giving testimony which is to serve as evidence in court proceedings or other proceedings conducted on the basis of a statutory law, gives false testimony or conceals the truth shall be punished by imprisonment for 6 months to 8 years.



**Appendix 5 to the Regulations of co-operation between the Medical Research Agency
and the external Experts**

THE EXPERT DATA FORM FOR SETTLEMENT PURPOSES.

**A. To be completed if the Expert makes an annual tax settlement in Poland
(otherwise delete or cross out):**

Form submission Form update

EXPERT

Names:				
Last name:				
Degree/ title:				
Personal Identification Number (PESEL):				
E-mail address ⁶ :				
Permanent residence address:	City/Town:		Postal Code:	
	Street:		Post office:	
	Building No.:		Apartment number:	
	Municipality:		District:	
	Voivodeship:		Country:	
Address of residence ⁷ :	City/Town:		Postal Code:	
	Street:		Post office:	
	Building No.:		Apartment number:	
	Municipality:		District:	
	Voivodeship:		Country:	
Correspondence address ⁸ :	Name of work establishment (if a specified address is the company one)			
	City/Town:		Postal Code:	
	Street:		Post office:	
	Building No.:		Apartment number:	
	Municipality:		District:	
Voivodeship:		Country:		
Bank name:				
Bank account No ⁹ : (legibly)				
Tax Office name:				
Tax Office address:				
Tax identifier (please select the appropriate option):	<input type="checkbox"/> PESEL – PERSONAL IDENTIFICATION NUMBER <input type="checkbox"/> Tax ID no. (.....) TIN (.....)			

⁶ The indicated e-mail address is also used by the MRA to provide the Expert with a PIT form after the end of the tax year. Please keep your e-mail address up to date if you change it.

⁷ Required, if different from the address of permanent residence.

⁸ Required, if different from the address of residence.

⁹ The amounts due for completed Orders shall be transferred to the specified bank account. Please enter legibly.



I am aware of the criminal and fiscal responsibility for providing false information, testifying untruthfulness or concealing the truth.

.....
date and legible signature of the
Expert

B. To be completed if the Expert makes an annual tax settlement in a country other than Poland (otherwise delete or cross out):

Form submission Form update

The provision of the following information is mandatory and required by the provisions of IFT-1R (i.e. "Information on the amount of revenue (income) obtained by natural persons not residing in Poland"), which will be issued by the MRA and sent to the Expert after the end of the tax year

EXPERT	
First name:	
Last name:	
Degree/ title:	
E-mail address: The indicated e-mail address is also used by the MRA to provide the Expert with a IFT-1R form after the end of the tax year. Please keep your e-mail address up to date if you change it.	
Father's first name:	
Mother's first name:	
Date and place of birth:	
Tax Identification Number:	
Document type and number:	<input type="checkbox"/> Insurance number <input type="checkbox"/> Passport <input type="checkbox"/> Official document confirming identity <input type="checkbox"/> Other type of tax identification <input type="checkbox"/> Other document confirming identity
The place of issue of the above-mentioned number:	
Expert's residence address	
Street and numbers:	
Postal Code:	
City/Town:	
Voivodeship/ Region:	



Country:	
Correspondence address (to be completed if different from the residence address)	
Name of company/ establishment – if applicable:	
Street and numbers:	
Postal Code:	
City/Town:	
Voivodeship/ Region:	
Country:	
Personal bank account No:	
Full name of account holder:	
Account no. (including IBAN):	
Name and address of the bank:	
SWIFT/BIC code:	

Declaration concerning tax

I hereby declare that I am a resident of *(country name)* and I declare all my income at the competent tax office in the area *(country name)*.....

I am aware of the criminal and fiscal responsibility for providing false information, testifying untruthfulness or concealing the truth.

.....
date and legible signature
of the Expert



Appendix 6 to the Regulations of co-operation between the Medical Research Agency and the external Experts

.....

Expert's name and surname

.....

date

Declaration

I hereby declare that I have read the document titled “Code of Ethics of the Medical Research Agency including elements of anti-corruption policy” and I undertake to abide by the provisions thereof.

.....

legible signature



Appendix 7 to the Regulations of co-operation between the Medical Research Agency and the external Experts

Expert remuneration table

No.	Task	Unit rates per task (gross, in PLN)
1.	Substantive assessment of the Project Co-Financing Application, along with a detailed justification of the awarded score	2,500.00
2.	Substantive assessment of the Project Co-Financing Application following an appeal	
3.	Substantive assessment of the Interim/Final Report	
4.	Substantive assessment of amendments to the Project Co-Financing Application	
5.	Participation in remote Project inspections	
6.	Participating in person in on-site inspections at the premises of the Project owner(s)	3,500.00
7.	Other ¹⁰	2,500.00

¹⁰ The order for expert activities in accordance with the scope defined in Art. 18 (1) or (1a) of the Act.
Medical Research Agency, ul. Chmielna 69, 00-801 Warsaw
e-mail: kancelaria@abm.gov.pl



Appendix 8 to the Regulations of co-operation between the Medical Research Agency and the external Experts

Procedure and terms of reimbursement of travel and accommodation costs

1. 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.
2. The reimbursement shall apply if the venue where the meeting of the Application Evaluation Team takes place is located outside of the Expert's town or city of residence.
3. Eligible for reimbursement shall be travel by the following means of transport:
 - a) rail, second class;
 - b) bus, coach, minibus – international or interurban routes;
 - c) private car;
 - d) air travel, economy class;
 - e) passenger boat (ferry), economy class.
4. In cases referred to in paragraph 3 (c) the Expert shall be eligible to receive reimbursement of travel costs in the amount equivalent to a product of the distance travelled in kilometres and the rate for one kilometre of mileage calculated in accordance with § 2 of the Regulation of the Minister of Infrastructure dated 25 March 2002 on the terms of calculating and reimbursing costs of using non-employer-owned passenger cars, motorcycles and mopeds for business purposes.
5. Reimbursement of accommodation costs within and outside of the Republic of Poland shall cover the maximum standard of a three-star hotel, guesthouse/motel etc. The cost of one night's hotel stay within the territory of the Republic of Poland shall not exceed PLN 600 gross, while the limit for the cost of a night's accommodation outside the Republic of Poland shall be determined as specified in appendix to the Regulation of the Minister of Labour and Social Policy dated 29 January 2013 on the amounts due to employees of state or local public sector institutions with regard to business travel.
6. The reimbursement of accommodation costs shall be made on the basis of invoices issued in the name of the Expert.
7. The original ticket or invoice with proof of payment shall be attached to the relevant Request for Reimbursement of Travel/Accommodation Costs (Appendix 9).
8. In the event of air travel, the Request for Reimbursement of Travel/Accommodation Costs shall be accompanied with the original airfare ticket and boarding passes.



9. The travel and accommodation reimbursement shall be made within 14 days of the date of filing the relevant Request for Reimbursement of Travel/Accommodation Costs along with the attachments.



Appendix 9 to the Regulations of co-operation between the Medical Research Agency and the external Experts

Request for Reimbursement of Travel/Accommodation

Costs

.....
(name and surname)

Finance and Accounting Department

.....
(address)

of the Medical Research Agency

.....
(contact phone no.)

I hereby request reimbursement of travel/accommodation costs ^(*) incurred in association with a meeting of the Application Evaluation Team:

1. Fare: ^(*)

Travel route:

.....

Means of transport^{**}:

Reimbursement amount: PLN

2. Costs of private vehicle use: ^(*)

I used a private vehicle, owned by me, make:, registration number: engine capacity:

I declare that the distance from to, ul., via the shortest route according to Google Maps, is: km.

Total distance, both ways: km.

Reimbursement amount: PLN

3. Accommodation costs: ^(*)

Dates according to invoice no.

.....

Reimbursement amount: PLN



Total reimbursement amount: PLN

Please transfer the amount due on the basis of the original ticket/invoice* attached hereto to the following bank account no.:

.....

.....

(Date and legible signature of the applicant)

(*) – delete as applicable

(**) reimbursement of economy class coach, bus, minibus, passenger boat (ferry) fare, second class rail fare or economy class airfare

Please find attached: (*)

Ticket, boarding passes, invoice with proof of payment