



*Dear Recipient,*

*This document has been developed as part of committed cooperation between the Medical Research Agency and the stakeholders from the medical trials industry. Its authors wished to create an inventory of widely accepted wording to facilitate the contracting process. This document is reviewed and developed on an ongoing basis. If you believe any passage merits clarification or have an idea on how to improve it, please send us your suggestion at psbk@abm.gov.pl. We hope that the involvement of the clinical research community will make it possible in the future to create a national template agreement that will be fully accepted by all parties to the contracting process.*

*When using this document, please bear in mind the following:*

* *This is a tripartite document.*
* *This document is a template intended to support the trial contracting process.*
* *This document is intended to address as many cases as possible; make sure to read it thoroughly and adapt it to your individual needs.*
* *You are free to introduce any kind of modification to the wording of this document.*
* *Any appendices must be developed by you.*
* *Wording in italics must be reviewed with particular care and suitably adapted to your particular trial or the specific nature of your organisation’s business.*
* *Fields marked … must be filled in with the relevant data.*

*We trust that this document will assist you in the process of contracting a clinical trial.*

*Project Team, Polish Clinical Trials Network*

**CLINICAL TRIAL AGREEMENT**

This agreement (hereinafter referred to as the “Agreement”) is made on the date of the last signature below (“Effective Date”) by and among:

\_\_\_\_ with its registered seat at …, entered in the Register of Entrepreneurs kept by the District Court for the capital city of Warsaw, 13th Commercial Division of the National Court Register, under number …….. REGON (National Business Registry No.)……….. NIP (Tax ID No.) ……………, hereinafter referred to as the “Site,” represented by \_\_\_ ,

and

\_\_\_\_ with its registered seat at … NIP ……………, hereinafter referred to as the “CRO/Sponsor”, represented by \_\_\_ ,

and

\_\_\_\_ domiciled at …………, PESEL (Personal ID No.):……………….., (conducting business as a registered entrepreneur under the name “………….,” entered in the Central Registration and Information on Business (CEIDG), NIP: ………, REGON: ………, with a registered office at ……………) hereinafter referred to as the “Principal Investigator,”

each individually referred to as a “Party” and jointly as the “Parties,”

who agreed as follows:

Whereas:

1. The Parties adopt the following definitions for the purposes of this Agreement:

|  |  |
| --- | --- |
| Study: | clinical trial [enter the name of the clinical trial] |
| Study Sponsor: | [enter the name and registered address of the Sponsor] |
| Sponsor’s Legal Representative: | [enter the name and registered address of the representative, if applicable] |
| Investigational Medicinal Product: | [enter the name of the IMP] |
| Protocol: | [enter Protocol name, title and number] |
| Place of Study conduct: | [enter place of Study conduct at the Site] |

1. *The Sponsor has requested the CRO to act for the Sponsor but on CRO’s own behalf while negotiating and concluding agreements with the Site and Principal Investigator;*
2. The CRO/Sponsor contracts the Principal Investigator to conduct the Study at the Site using the Investigational Medicinal Product in accordance with the Protocol;
3. The Principal Investigator is prepared to conduct the Study in accordance with the Protocol and the Site agrees to have it conducted on its premises as specified in this Agreement.

**Section 1 Subject matter of the Agreement**

1. The subject matter of this Agreement is the Parties’ cooperation as part of the Study being performed by the Principal Investigator at the Site, in accordance with the Protocol and applicable laws.
2. Unless otherwise specified in the Agreement, capitalised terms shall have the meanings ascribed to them in 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 and in the recitals hereof.
3. The CRO/Sponsor hereby entrusts to the Principal Investigator the conduct of the Study in accordance with the Agreement, the Protocol and the applicable laws. During the Study, the Site undertakes to cooperate with the Sponsor, CRO, Principal Investigator and Study Team in accordance with the Agreement, the Protocol and the applicable laws.
4. The Principal Investigator undertakes to conduct the Study in accordance with the Protocol, the applicable laws and the instructions of the CRO/Sponsor. With regards to the Study conduct, the Principal Investigator and Study Team shall not act as the Site’s employees. The Principal Investigator and Study Team shall be considered independent contractors for the services connected with the Study conduct. The Protocol, in the version applicable as at the date of the Agreement, constitutes Appendix No. 1 hereto.
5. The planned duration of the Study: from … to ….
6. The Parties expect that under this Agreement, the Study shall recruit … Subjects, to be enrolled at the Site, meeting all eligibility criteria specified in the Protocol. Enrolling a larger number of Study Subjects shall require approval of the CRO/Sponsor expressed in writing or in other documentary form.
7. The Parties acknowledge that national, foreign or international authorities involved in supervising or controlling clinical trials, as well as independent auditors appointed by such authorities or by the Sponsor, may perform audits or inspections of the Study-related procedures, devices and documents, including medical records of all the Subjects, within the working hours of the Site’s administration.
8. The Parties also acknowledge that Study monitors or other assignees of the CRO/Sponsor may, within the working hours of the Site’s administration, perform reviews and inspections of the Site’s infrastructure used to perform the Study, as well as of the data and results of the Study-related activities, in order to ensure that the Study is being conducted in accordance with the Protocol, the Agreement and the applicable laws.
9. By signing this Agreement, the Site and the Principal Investigator represent that they have received the Study Protocol, and the Principal Investigator also declares to have read and accepted it. The Sponsor reserves the right to introduce written changes to the Protocol (listed in protocol amendments) that will subsequently apply during the performance of the Study. Any amendment to the Protocol shall be immediately communicated in writing by the CRO/Sponsor to the Principal Investigator and the Site, no later than within 14 days of introducing the amendment.

**Section 2 Investigational Medicinal Product**

1. The CRO/Sponsor shall ensure the Principal Investigator is provided with the relevant quantities of the Investigational Medicinal Product and auxiliary medicinal products necessary to perform the Study, to be delivered to the Site pharmacy, where the Investigational Medicinal Product shall be documented, prepared and stored in accordance with the law and the Protocol. The Site or the Principal Investigator shall not use the Investigational Medicinal Product for any other purpose except conducting the Study.
2. The Principal Investigator undertakes to only use the Investigational Medicinal Product in the manner specified in the Protocol. The Principal Investigator warrants that the Investigational Medicinal Product shall be dispensed, documented and stored in the appropriate conditions in accordance with the Protocol and the applicable regulations.
3. Once the Agreement expires or is terminated, the Principal Investigator shall immediately return any unused Investigational Medicinal Products to the CRO/Sponsor at the Sponsor’s cost and upon the Sponsor’s instructions. Should the Investigational Medicinal Products supplied for the purposes of the Study need to be disposed of, the CRO/Sponsor shall cover the relevant costs in accordance with the price list applicable at the Site and shall issue the necessary instructions.

**Section 3 Responsibilities of the CRO/Sponsor**

1. The CRO/Sponsor undertakes to:
	1. provide the Site and Principal Investigator with the complete Protocol. If the Protocol is provided in English, the CRO/Sponsor shall have the Protocol Synopsis translated into Polish;
	2. provide the Site and Principal Investigator, no later than 14 days before the planned date of first patient recruitment, with an official approval of the Study and a favourable opinion of the competent Ethics Committee;
	3. give notification of the Study registration number in the Central Register of Clinical Trials;
	4. notify the Site and Principal Investigator of the name and contact details of the Study Monitor at the beginning of the Study and each time the Monitor is replaced;
	5. provide the Principal Investigator with complete documentation necessary to conduct the Study, including the Protocol and Investigator’s Brochure, within a time that makes it possible to get acquainted with the way the Study is to be conducted;
	6. organise an initiating visit and train the Principal Investigator and members of the Study Team to ensure correct performance of the Study at the Site;
	7. provide ongoing information that can affect the safety of the Subjects and the course of the Study;
	8. collect any unused or expired Investigational Medicinal Product supplied for the purposes of the Study or cover the costs of its return or disposal;
	9. notify the Site within the agreed reporting periods of the number of Subjects and their completed visits, as well as of the procedures performed, including optional ones, as referred to in Appendix No. 2 hereto, along with the dates of such visits and procedures, including optional ones, and the Study completion date (end of the active phase and closing the Study at the Site);
	10. if Study data are to be processed using methods based on IT systems, the CRO/Sponsor shall provide the members of the Study Team with free access to these systems along with written instructions of use;
	11. provide the equipment and devices to be used in the Study, as specified in Appendix No. 3 hereto.
2. The CRO/Sponsor represents that, other than this Agreement and the circumstances set forth herein, CRO andthe Sponsor shall not enter into any legal relationship with the Principal Investigator or members of the Study Team with regard to the performance of the Study at the Site, nor shall they make any additional payments to the Principal Investigator or members of the Study Team for performing the Study at the Site other than the payments contemplated herein.

**Section 4 Responsibilities of the Principal Investigator**

1. The Principal Investigator undertakes to:
	1. conduct the Study in accordance with the Protocol and the applicable laws;
	2. adhere to any instructions regarding the conduct of the clinical trial received from the CRO/Sponsor or set forth in Good Clinical Practice;
	3. perform the Study, which includes Subject recruitment, performing services specified in the Protocol and Investigator’s Brochure, providing – in cooperation with the Site – proper medical care to the Subjects during the Study, completing CRFs and reporting about Study progress to the CRO/Sponsor;
	4. comply with the principles of collecting, reporting and storing data as set forth in this Agreement, the Protocol and commonly applicable laws, within the timeframes and according to the requirements specified by the CRO/Sponsor;
	5. ensure protection of data, including personal information of the Subjects collected as part of the Study conduct;
	6. disclose, upon each request of the CRO/Sponsor, any materials and studies collected and developed as part of performance hereunder;
	7. notify the CRO/Sponsor of any Protocol deviations.
2. The Principal Investigator shall appoint a study team as necessary to perform the Study, exhibiting the necessary skills and qualifications (the “Study Team”). The composition of the Study Team is specified in Appendix No. 4 hereto. Modifying the composition of the Study team shall not require amending this Agreement, yet the Principal Investigator shall be required to inform the other Parties each time the composition of the Study Team is changed. The Principal Investigator represents that every member of the Study Team shall abide by the provisions of the Agreement and the Protocol. The Principal Investigator shall be liable for the actions or omissions of the Study Team during the conduct of the Study as if they were the Principal Investigator’s own actions or omissions.
3. The Principal Investigator shall exercise direct supervision over the correct performance of the activities entrusted by him/her to selected members of the Study Team and shall evaluate and accept the work once delivered.
4. The Principal Investigator represents to have the necessary qualifications and licences to act as the investigator, which can be evidenced upon the CRO/Sponsor’s request by producing the relevant documents, as required by the applicable laws.
5. If a Serious Adverse Event (SAE) occurs, the Principal Investigator undertakes to adhere to the instructions contained in the Protocol and to report the event immediately to the Site and CRO/Sponsor within 24 hours of becoming aware of such event. In the event of receiving queries from the CRO/Sponsor regarding adverse events, the Principal Investigator shall respond without delay to any questions to the best of his/her knowledge.
6. The Principal Investigator shall be responsible for storing Study files in accordance with the applicable laws and the Protocol.
7. The Principal Investigator shall perform this Agreement in person and shall not assign any rights or obligations arising herefrom without a prior written consent from the CRO/Sponsor and the Site.
8. When conducting the Study, the Principal Investigator shall always exercise his/her best professional judgment, in compliance with the Study requirements, in relation to all individuals participating in the Study.
9. The Principal Investigator represents that no proceedings are currently pending that could lead to the Principal Investigator’s debarment or suspension of his/her medical licence. The Principal Investigator represents that as part of performance hereunder he/she shall not procure services from any person known by the Principal Investigator to have been debarred or suspended.
10. The Principal Investigator represents and warrants that the conclusion of this Agreement shall not give rise to any conflict of interest either for the Principal Investigator or for the members of the Study Team and that he/she shall immediately notify the Parties of any emerging conflicts of interests for the Principal Investigator or members of the Study Team.
11. *The Principal Investigator undertakes to establish the amount of remuneration for the members of the Study Team on the basis of the actual workload of individual members of the Study Team and shall provide the CRO/Sponsor with a relevant list within the agreed billing periods. The CRO/Sponsor shall conclude appropriate cooperation agreements with the members of the Study Team.*
12. The Principal Investigator undertakes while performing hereunder to act in accordance with the Site’s internal regulations, in particular those regarding the conduct of clinical trials at the Site.

**Section 5 Responsibilities of the Site**

1. The Site undertakes to cooperate with the Sponsor, CRO and Principal Investigator in performing Study-related activities, in particular to:
	1. allow the Study to be conducted, which includes making available qualified medical staff and access to appropriate premises, equipment and devices. The equipment and devices made available for the purposes of the Study shall meet the relevant technical requirements, have valid certificates and undergo maintenance in accordance with current requirements. At the request of the CRO/Sponsor, the Site shall produce the relevant certificates for the equipment or devices;
	2. provide medical services as set forth in the Protocol and ordered by the Principal Investigator;
	3. provide pharmaceutical surveillance over the Study in accordance with the law;
	4. supervise the development of medical records constituting source documentation for the Study;
	5. be prepared to enable the Principal Investigator to provide immediate medical assistance to the Subjects at the Site.
2. The Parties agree that the Site shall archive Study records in return for the remuneration specified in Appendix No. 2 hereto for a period of 25 years from the date of Study completion at the Site. After the above period, the CRO/Sponsor shall collect the Study records at its own cost. Upon the request and at the cost of the CRO/Sponsor, the Site may destroy Study records. In the event that, despite two calls sent in writing by the Site for the CRO/Sponsor to collect Study records, the CRO/Sponsor does not collect the records or request their destruction within 3 months of the date of postage of the second call, the Site shall be entitled to destroy the Study records at the cost of the CRO/Sponsor.

**Section 6 Personal data, confidentiality and intellectual property**

1. The Parties undertake to abide by all applicable laws associated with personal data protection and use and with data privacy while performing hereunder. The principles of processing personal data, in particular personal data of the Subjects, are specified in Appendix No. 5 hereto.
2. During the term of this Agreement and for the period of ten (10) years from the end of the Study at the Site, the Principal Investigator and the Site shall keep confidential any information received from the CRO/Sponsor or generated as part of the Study (“Confidential Information”). The above restriction shall not apply to Confidential Information which:
	1. has been made public without the involvement of the Principal Investigator or the Site;
	2. has already been in the possession of the Principal Investigator or the Site;
	3. is required to be disclosed by law;
	4. has been provided to the Principal Investigator or the Site in accordance with the law;
	5. has been disclosed in accordance with this Agreement.
3. The results and data of the Study conducted hereunder shall be the sole property of the Sponsor. The Principal Investigator undertakes to provide to the CRO/Sponsor any results and Study data in the form agreed with the CRO/Sponsor.
4. The Sponsor shall publish information about the Study, including data that can be made public, at www.clinicaltrials.gov. The published information shall be publicly available on the said website before the first Subject is enrolled in the Study. The CRO/Sponsor shall ensure the published data about the Study are kept up to date to provide complete and valid information.
5. The Site may publish basic information about the Study on its website, to the extent equivalent to the clinical trial information published at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).
6. *Any publication or public presentation of the Study results by the Principal Investigator requires prior consent from the CRO/Sponsor.*

**Section 7 Financing health care services and Study insurance**

1. *CRO represents that* the Sponsor shall fund any Study-related health care services required by the Protocol, in accordance with the law, including health care services necessary to treat the adverse effects of the Investigational Medicinal Product emerging as a result of procedures performed solely for the purposes of the Study.
2. *CRO represents that* the Sponsor has concluded an insurance contract to insure the Sponsor and the Principal Investigator against any damage arising in connection with the Study, in accordance with the applicable laws, and the Sponsor shall ensure continuity of insurance coverage throughout the Study. A copy of the insurance policy constitutes Appendix No. 6 hereto. The CRO/Sponsor is obliged to deliver to the Site and Principal Investigator a certificate/amendment extending the insurance policy before the previous policy expires.
3. The Site holds a third party insurance required by the applicable Polish law.

**Section 8 Remuneration and payment terms**

1. For the performance hereof, the CRO/Sponsor shall pay the Site, the Principal Investigator and the members of the Study Team the remuneration specified in Appendix No. 2 hereto (“Study Budget”).
2. A detailed Study Budget and payment schedule for the Site, Principal Investigator and Study Team are contained in Appendix No. 2 hereto.
3. Any Protocol amendment that would affect the scope of responsibilities of the Principal Investigator or the Site, in particular any changes that necessitate revisiting the costs of the Study, shall require amending this Agreement to adjust the remuneration due to the Principal Investigator and the Site accordingly.

**Section 9 Term and termination**

1. This Agreement is made for a fixed term, until the date of Study completion at the Site.
2. The Parties mutually agree that this Agreement shall enter into force on the day it is signed by all Parties, except that the respective rights and obligations of the Parties arising herefrom (save for the confidentiality obligation) shall be suspended until the day the CRO/Sponsor provides the Site and Principal Investigator with:
	1. an official approval of the Study;
	2. a favourable opinion on the Study issued by an Ethics Committee.
3. The CRO/Sponsor shall be entitled to stop the Study at any time. If this is the case, this Agreement shall be dissolved on the date the Site or the Principal Investigator (whichever is later) receives a written notification of Study termination from the CRO/Sponsor. In this situation, the settlements among the Parties shall be based on a study progress protocol prepared by the Parties as of the Study termination date, specifying e.g. the number of visits completed until that time by each Subject and the health care services performed for the purposes of the Study.
4. Each Party shall be entitled to terminate this Agreement by 30 days’ written notice in the event of non-performance or undue performance hereof by the other Parties hereto. This entitlement shall apply upon the ineffective lapse of 30 days from sending to the defaulting Party a notice calling for due performance of its obligations.
5. Each Party shall be entitled to terminate this Agreement for an important reason by 90 days’ written notice.
6. Any provisions of this Agreement necessary to construe and enforce the rights and obligations of the Parties resulting herefrom to the extent required to fully comply with and perform this Agreement, shall survive the termination hereof.

**Section 10 Final provisions**

1. All amendments and additions to this Agreement must be done in writing under the pain of nullity.
2. This Agreement shall be governed by the Polish law and construed according to the generally applicable provisions of the Polish law.
3. Any notices and other information resulting from this Agreement shall be provided in writing to the address specified below and shall be considered served also if delivered in person or by email, or if sent by registered mail. Any notices and other information resulting from the Agreement shall be deemed served as soon as they are received by the addressee, and if not collected by the addressee – after 14 days of the first delivery attempt. The said notices must be duly addressed to the following addresses of the Parties:

If to the CRO/Sponsor:

 ………………………………………………………….

If to the Principal Investigator:

 …………………………………………………………..

If to the Site:
 …………………………………………………………..

1. The Parties agree that the court competent for any possible disputes arising from or in connection with this Agreement shall be the common court having jurisdiction over the registered office of the Site.
2. This Agreement is drafted in Polish and English, one copy for each Party. In the event of any discrepancies between the Polish and English version of the Agreement, the Polish version shall prevail.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

For the CRO/Sponsor

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

For the Site

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator

(signatures of the Parties and signature date)

Appendices:

1. Protocol,
2. Study budget,
3. Supply of equipment/devices by the CRO/Sponsor,
4. Composition of the Study Team,
5. Principles of personal data processing,
6. Copy of Study insurance policy.