CONTRACT

between

the **Company/Organisation ...** (referred to hereafter, for reasons of brevity, as the "Commissioning body") with its head office in ..., Via ..., VAT number ..., Fiscal code ..., represented by ..., born... on ..., is authorised to sign the present contract with ...

and

the **Department of ... University of Pavia** (referred to hereafter, for reasons of brevity, as the "Department"), Fiscal code. ..., based in Pavia, Via ..., represented, in accordance with and for the purposes set out in Art. 8, subparagraph 17, of the Manual attached to the Regulations of the University regulations for administration, finance and accounting, by Director Prof. ..., born in ..., on ..., authorised to sign the present act by Department board decision dated ...

hereafter, referred to jointly as "parties" and individually as "party"

the following is agreed and stipulated

- the Department is involved in theoretical and experimental research activities in ...;
- the commissioning body carries out research in ...;
- the commissioning body is interested in carrying out clinical testing on ..., in accordance with the provisions of the present contract, the attached protocol[2] and the relative laws and provisions in force;
- the Department is interested in carrying out clinical testing on ..., and declares that it possesses the organisation, instrumentation and competence necessary for the execution of said testing, adhering to the regulations as established in D. Lgs. 211/2003 (actuation of directive 2001/20/UE relative to the application of good clinical practice in the execution of testing of medicines for clinical use) and subsequent modifications and integrations, as well as D. Lgs. 196/2003 (Code on the protection of personal data and the protection of privacy) and the attached protocol;

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1 Regarding experiments on animals, the contract, in the premises (from the fourth to the sixth dash) and in the articles (art. 4, from the third dash until the end of the Article; art. 6, III formulation, II comma; art. 7, II and III commas, art. 11, II comma), should be modified to adhere to the relative laws in force. In particular: D. Lgs. 116/92 (Actuation of directive n. 86/609/CEE relative to the protection of animals used in experiments or other scientific purposes) and L. 96/2013 (Governmental mandate for the transposition of European directives and the actuation of other European Union acts – European Delegated Regulation 2013), art. 13 (Governmental mandate criteria for the transposition of *Dir. 2010/63/UE* relative to the protection of animals used for scientific purposes) as well as, adhering to the University of Pavia's internal regulations, the document "Regulations for the use of animals in experiments and in scientific research", with particular regard to the obligation to acquire prior approval from the university's ethics committee for testing on animals.

2 Protocol, in this contract, refers to the testing protocol detailing the testing criteria and methods.

– the commissioning body has obtained a favourable outcome from the University's Ethics Committee with the issuing of an authorisation document, in accordance with the provisions established in Art. 6 of D. Lgs n. 211/2003, in sitting ...;
– the clinical testing provided for in the present contract and conducted on patients at the University departments concerned may only be carried out in full respect of the Dignity of the Human Being regulations and his/her basic rights as set out in the Helsinki Accords and subsequent amendments, the "*Good Clinical Practice*" (GCP) regulations emanated by the European Union (as they were come transposed by the Italian government pursuant to the guidelines emanated by the same bodies), as well as in the actuation of the provision established by the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: stipulated at Oviedo (4 April 1997) and the Italian Medical Code of Ethics for the health professions.

The following is agreed and stipulated

Article 1– Premises and attachments

The premises and Protocol attached to the present contract are an integral and significant part of the contract, even for purposes of interpretation.

Article 2 – Contract scope

I Wording: The commissioning body entrusts the Department with the execution of the experiment entitled: "..." (hereafter referred to as "clinical experiment"), pursuant to the programme detailed in the attached Protocol (att. 1), an integral and significant part of the contract.

Or

II Wording: The commissioning body entrusts the Department with the execution of the experiment entitled: "..." (hereafter referred to as "clinical experiment"), pursuant to the following programme

Article 3 – Scientific supervision The parties agree that the clinical experiments will be conducted at the Department under the supervision of Prof. ... (hereafter referred to as "Testing supervisor").

The commissioning body's contact will be Dott. ... delegated to ... represent the commissioning body in all its transactions with the Department.

Article 4 – The department's obligations

The Department is committed to:

- make available, for the execution of the activities related to the clinical tests, its personnel, equipment and all necessary instruments, putting into practice all its relevant know-how and experience;
- enrol the patients who will participate in the clinical tests in accordance what is established in Art. 2 of the Protocol;

- provide adequate information to the patients participating in the clinical test as to the objectives, methods, benefits and potential risks and inconveniences deriving from said tests;
- ensure that patients participating in the clinical tests have signed the informed consent document of their own accord, pursuant to the template attached in the Protocol;
- gather the data relative to the clinical tests conduct on each patient and complete the relative clinical case history and Data Collection Sheet, respecting the timescale and criteria detailed in the Protocol;
- observe the applicable regulations stating that the commissioning body, as promoter of the testing, should be informed of any adverse events or serious adverse reactions, in adherence with the procedure defined in the Protocol. In particular, the Department is obliged to inform the commissioning body, as promoter of the clinical tests, of any patient deaths, providing any additional information that may be requested;
- conserve for a period of ... years ... the clinical test documents (***N.B.*** → *for tests on humans, this period should not be inferior to seven years, in accordance with the directives defined in the "Guidelines for the handling of personal data relative to clinical testing of medicines" – Del. N. 52 of 24 July 2008*)

Article 5 – The commissioning body's obligations

The commissioning body is committed to:

- providing the Department, at its own duty and expense, the required quantity of the product in order to carry out the clinical test;
- deliver the product, in the set quantity, to the Department adhering to the instructions the Department has provided;
- use the product exclusively for the purposes of the clinical test itself and return the outstanding product stocks should be contract be terminated early, for whatever reason,;
- provide and deliver to the Department the scientific materials necessary to carry out the clinical test, as well as any eventual equipment needed to administer the product.

Article 6 – Payments

I Wording: The commissioning body commits to paying the Department for the execution of the activities defined in the present contract, the following amounts:

- a payment of € ... + VAT for each patient correctly enrolled, completed and evaluated.

Or

II Wording: The commissioning body commits to paying the Department for the execution of the activities defined in the present contract, the amounts agreed by the Parties and indicated in the Reimbursements table found in the attached Protocol.

Or

III Wording**:** The commissioning body commits to paying the Department for the execution of the activities defined in the present contract, the following amount/amounts in the following instalment timeframe: ...

It should be noted that the amounts detailed above are inclusive of all expenses borne for the laboratory exams and instrumental screening provided for by the Protocol.[3]

Should the contract be terminated or one party withdraw from the contract, the Department will have the right to be compensated for any clinical testing already conducted, based on the number of cases handled and in proportion to the stage of progress.

The commissioning body is contracted to make a payment, via bank transfer to account holder at ..., ... Bank, ... branch (eventual address), to IBAN ... (→ for public organisations, Bank of Italy Unified Public Treasury current account).

Article 7 – Liability and insurance

Each party will provide for personal injury cover and liability insurance versus third parties for its own personnel who, in virtue of the present contract, are employed at the sites where the work is carried out. University staff benefit from INAIL/ Workers Compensation Authority cover and are also covered by liability policy insurance.

The commissioning body, as promoter of the clinical tests disciplined by the present contract, declares and ensures that it has suitable insurance cover to compensate recruits for any damage they may incur during clinical tests and suitable liability cover for recruits, authorised by the Department and the commissioning body.

The commissioning body covers, therefore, the Department against all proceedings that may be brought by patients who incur damage that derives from their participation in the tests, except in cases where:

- damage is due to negligence, carelessness, fraudulent acts, failure to observe internal university regulations, norms and provisions;
- damage due to failure to respect the Protocol.

[University staff injured during the clinical tests defined in the present contract, conducted in the relevant Departments, adhering to the methods and timescales established by the regulations and provisions currently in force, should report the injury to their competent INAIL office. If the injury regards commissioning body personnel working at the university department were the clinical tests are being conducted, the university should report the incident to the relevant INAIL office, respecting the timescale and methods established by the regulations and provisions currently in force. The university should also inform the other party. The same process applies in instances where university staff work at the commissioning body's premises for activities related to the clinical tests.]

Article 8 – Health and safety in the workplace

The Testing supervisor, pursuant to Art.26 of D. Lgs. 81/2008 and subsequent modifications and integrations, is obliged to ensure the health and safety of those involved in the execution of the present contract, including exercises on risk prevention and protection for personnel exposed to risk in their place of work, pursuant to University regulations regarding safety

[3] With regard to the patenting of results deriving from the clinical testing, refer to the research contract template (last comma of art. 4).

management and prevention in tenders, contracted works and supply contracts.

Any commissioning body personnel operating at the Department's premises should observe the regulations, norms and provisions with regard to health and safety currently in force at the university.

The commissioning body's supervisor, conforming to the provisions established in Art. 26 of D. Lgs. 81/2008, co-operating in the actuation of prevention and protection measures regarding risks related to clinical testing should highlight the health and safety issues of the workplace to those destined to work in them.

The commissioning body's supervisor should also ensure that the host university personnel correctly apply preventative and emergency measures and diligently observe the relevant laws and provisions currently in force and the regulations at the commissioning body's premises.

Article 9 – Confidentiality

Taking into consideration what is set out in Art. 12, the Department is committed to guaranteeing the confidentiality of all information, technical data and documentation concerning the commissioning body in the execution of the tasks connected to the present contract as well as the results obtained from the clinical testing.

Article 10 – Rights and publication

The parties agree that all the results that derive from the clinical testing will be the property of the commissioning body and cannot, in any way, be ceded or communicated to third parties, divulged or appear in scientific publications/conference materials without the prior written consent of the commissioning body.

Regarding any eventual patenting of results, taking for granted the moral right of the inventor to be recognised as such, in adherence to laws currently in force, the Department is committed to recognising the commissioning body's rights once any eventual patents are granted and ceding to it the relative industrial exploitation of these rights.[4]

Article 11– Handling of personal data

Clinical testing is conducted in conformity with the laws currently in force regarding to the handling of personal data (D. Lgs 196/2003 – Code on the protection of personal data and the protection of privacy).

Pursuant to the cited law, the Department will act as the safeguarder of the handling of patients' personal data, ensuring the respect of the relevant regulations, including those concerning sensitive information.

The commissioning body, in turn, safeguards privacy rights and protects personal and sensitive data, fully respecting current laws and will act a the entity responsible for the handling of such information.

Article 12 – Duration and withdrawals

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[4] With regard to the eventual patenting of results, it is possible to foresee the payment method of any flat-fees or royalties from the commissioning body to the Department that derive from the commercialisation of patented products. In such cases, refer to the template for research contracts (Art. 7, I wording).

The present contract comes into effect when signed and can be considered no longer valid at the end of the testing period, as defined in the Protocol.

Either party may withdraw from the present contract by providing written communication to the other party sent by recorded delivery with at least ... days before the date on which the withdrawal should come into effect.

It should be stressed that the Department may withdraw, with giving prior notice, should the commissioning body declare itself bankrupt, be subject to insolvency proceedings, in cases of insolvency, where an extrajudicial bankruptcy agreement has been proposed and enforceable proceedings have begun and, on the part of the commission body, whenever these procedures arise through factors related to patient safety during clinical testing or whenever competent institutions request the interruption of the experiments.

The withdrawal will be effective from the date written communication is received.

Article 14 – Termination for breach of contract

Should the Department fail to fulfil any of its obligations as defined in the present contract and fails to resolve the situation within 15 days of the receipt of a letter of formal notice from the commissioning body, sent via recorded delivery, the present contract, pursuant to Art. 1454 c. c., is considered terminated.

Article 16 – Registration and duty stamps

The present contract is subject to duty stamps, in accordance with Art 2, comma 1, of D.P.R. 642/72, to be borne by the commissioning body

The present contract is subject to registration only when it is used and on fixed Registration Tax terms, in accordance with Articles 5 and 39 D.P.R. n. 131/86, in accordance with Art. 11, Part I tariff, of the cited DPR, as they are contractual services subject to VAT, with the expenses to be borne by the commissioning body.

Article 15 – Applicable laws and jurisdiction

The contract is subject to Italian law.

Even though not expressly established in the present contract, Civil Code provisions apply.

The Tribunal of Pavia will have jurisdiction in any disagreements that may arise between the parties in relation to the interpretation, execution and/or validity of the present contract that cannot be resolved amicably.

Pavia, __/__/____

Commissioning body ...	Department of ...
Legal representative	University of Pavia
	Director
_____	_____
(Dott. ...)	(Prof. ...)

Contingent

Although the clauses in the present contract derive from negotiations between the parties, the parties declare, pursuant to Articles 1341 and 1342 of the Civil Code, that they fully approve the provisions contained in the articles ...

Commissioning body ...	Department of ...
Legal representative	University of Pavia
	Director
_____	_____
(Dott. ...)	(Prof. ...)