Clinical Trial Agreement

This **Clinical Trial Agreement** (“***Agreement***”) is entered into as of _____ ("***Effective Date***"), by and between the following parties:

Sponsor

_____

_____ _____

_____ _____ _____ _____

_____ _____

Institution

_____

_____ _____

_____ _____ _____ _____

_____ _____

Sponsor and Institution may be referred to individually as a “***Party***” and collectively as the “***Parties.***”

1. Purpose and Scope

The purpose of this Agreement is to define the terms and conditions under which Institution will conduct a clinical trial sponsored by Sponsor in accordance with the protocol titled “_____” (“***Protocol***”).

The clinical trial (the “***Study***”) will be conducted under the supervision of _____ _____ (“***Principal Investigator***”), who is affiliated with Institution.

2. Study Conduct

Institution shall conduct the Study:

- In accordance with the Protocol, as may be amended from time to time with Sponsor’s approval
- In compliance with all applicable laws, regulations, ethical standards, and guidelines
- In accordance with good clinical practice standards and institutional policies
- The Principal Investigator shall have primary responsibility for the conduct of the Study at Institution.

Institution shall ensure that all personnel involved in the Study are appropriately qualified and trained.

3. Responsibilities of the Sponsor

Sponsor shall:

- Provide the Protocol and all necessary study-related documentation
- Supply investigational products, if applicable, in sufficient quantities
- Provide necessary training and information regarding the Study
- Monitor the conduct of the Study to ensure compliance with the Protocol and applicable standards
- Make payments to Institution in accordance with the Payment clause

4. Responsibilities of the Institution

Institution shall:

- Conduct the Study in accordance with the Protocol and applicable standards
- Obtain all necessary approvals from ethics committees or institutional review boards prior to initiating the Study
- Ensure that informed consent is obtained from all Study participants before their participation
- Maintain accurate and complete records related to the Study
- Permit Sponsor or its representatives to review Study records for monitoring and audit purposes

5. Study Timeline

The Study shall commence on _____ and continue until completion in accordance with the Protocol, unless terminated earlier in accordance with the Termination clause.

Institution shall use reasonable efforts to meet enrollment targets and timelines specified in the Protocol.

6. Payment and Financial Terms

Sponsor shall compensate Institution for the performance of the Study as follows:

Description of Activity	Payment Amount	Payment Schedule
Study start-up activities		
Per subject enrolled		
Study completion activities		

Payments shall be made within [Number] days following receipt of a valid invoice from Institution.

7. Investigational Product

If the Study involves an investigational product Sponsor shall supply the investigational product and related materials.

Institution shall:

- Store, handle, and use the investigational product in accordance with Sponsor's instructions and applicable regulations
- Maintain accurate accountability records
- Not use the investigational product for any purpose other than the Study

8. Confidentiality

Each Party agrees to keep confidential any non-public, proprietary, or sensitive information disclosed by the other Party in connection with this Agreement.

Confidential information shall not be disclosed to any third party without prior written consent, except where required by law or regulatory authorities.

This obligation shall continue for _____ years after termination or completion of the Study.

9. Data Ownership and Use

All data generated from the Study shall be owned by Sponsor.

Institution and Principal Investigator may use Study data for academic and research purposes, provided that:

- Sponsor's confidential information is protected
- Any publication complies with the Publication clause

10. Publication

Institution and Principal Investigator shall have the right to publish the results of the Study. Prior to submission for publication, Institution shall provide Sponsor with a copy of the proposed publication for review at least _____ days in advance.

Sponsor may request reasonable modifications to protect confidential information or intellectual property.

11. Adverse Events and Reporting

Institution shall promptly report any adverse events, serious adverse events, or safety concerns in accordance with:

- The Protocol
- Applicable regulatory requirements

Institution shall cooperate with Sponsor in investigating and addressing such events.

12. Insurance and Indemnification

Sponsor shall maintain appropriate insurance coverage for the Study, including coverage related to the investigational product, where applicable.

Sponsor agrees to indemnify and hold harmless Institution, its employees, and the Principal Investigator against claims arising from:

- The use of the investigational product
- The design of the Study

except to the extent such claims result from negligence, misconduct, or failure to comply with this Agreement by Institution or its personnel.

13. Termination

Either Party may terminate this Agreement:

- For convenience, upon _____ days' prior written notice
- For cause, if the other Party materially breaches this Agreement and fails to cure the breach within a reasonable period after receiving notice

Sponsor may terminate the Study immediately if:

- There are safety concerns
- Regulatory authorities require termination
- The Study is no longer scientifically or commercially viable

Upon termination:

- Institution shall cease all Study-related activities as instructed by Sponsor
- Sponsor shall pay Institution for all work properly performed up to the date of termination
- All investigational products and confidential materials shall be returned or disposed of as directed by Sponsor

14. Compliance with Laws

Each Party shall comply with all applicable laws, regulations, and ethical standards in performing its obligations under this Agreement.

Institution shall ensure that the Study is conducted in accordance with applicable health, safety, and data protection requirements.

15. Independent Contractor Relationship

The Parties are independent contractors. Nothing in this Agreement creates any partnership, joint venture, or employment relationship between the Parties.

16. Governing Law and Dispute Resolution

This Agreement shall be governed by and interpreted in accordance with the laws of _____.

Any disputes arising out of or in connection with this Agreement shall be resolved through good faith negotiations between the Parties. If a resolution cannot be reached, the dispute shall be submitted to the competent courts of _____.

17. Entire Agreement

This Agreement constitutes the entire understanding between the Parties regarding the Study and supersedes all prior agreements or understandings, whether written or oral.

18. Amendments

This Agreement may be amended only by a written document signed by authorized representatives of both Parties.

19. Notices

All notices under this Agreement shall be in writing and delivered to the addresses of the Parties set forth above or to such other address as either Party may designate in writing.

20. Signatures

IN WITNESS WHEREOF, the Parties have executed this Clinical Trial Agreement as of the Effective Date.

Sponsor

Name

Date

Signature

Institution

Name

Date

Signature

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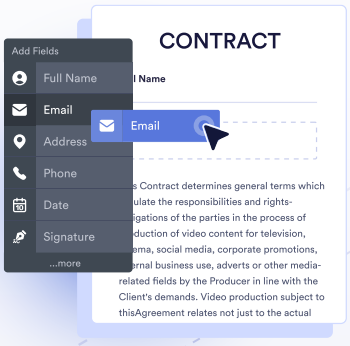

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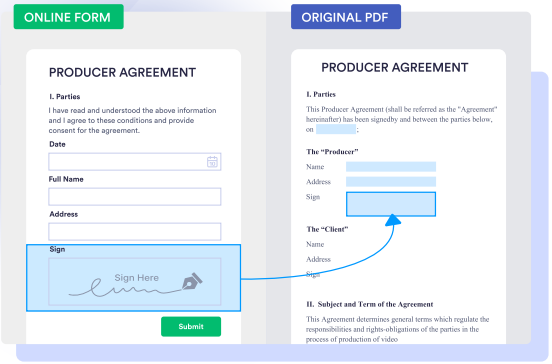

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