46-Clinical Trial Agreement: Governs terms of clinical research studies.

Clinical Trial Agreement

Effective Date: [Date]

Between:

Sponsor: [Sponsor's Full Name or Company Name], located at [Sponsor's Address].

Institution/Site: [Institution's Full Name], located at [Institution's Address].

Principal Investigator: [Principal Investigator's Full Name], located at [Institution's Address].

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1. Purpose and Scope of the Agreement

- **1.1 Purpose**: This Agreement sets forth the terms and conditions under which the Institution will conduct a clinical trial (the "Study") sponsored by the Sponsor to evaluate [Description of the Study, e.g., investigational product, treatment, or device].
- **1.2 Study Protocol**: The Study shall be conducted in accordance with the protocol titled **[Protocol Title]**, identified by protocol number **[Protocol Number]**, as attached in Exhibit A (the "Protocol").
- **1.3 Regulatory Compliance**: The Study shall be conducted in compliance with all applicable laws and regulations, including but not limited to:
    - The U.S. Food and Drug Administration (FDA) regulations.
    - The International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines.
    - Any other applicable regulatory bodies and ethical standards.

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2. Responsibilities of the Parties

- **2.1 Sponsor’s Responsibilities**: The Sponsor agrees to:
    - **a.** Provide all necessary funding, materials, and investigational products to the Institution to conduct the Study.
    - **b.** Supply the Protocol, informed consent forms, and any regulatory documentation required for the Study.
    - **c.** Monitor and oversee the conduct of the Study as required by regulatory authorities.
- **2.2 Institution’s Responsibilities**: The Institution and the Principal Investigator agree to:
    - **a.** Conduct the Study in accordance with the Protocol, applicable regulations, and ethical standards.

- **b.** Ensure that all Study personnel are appropriately trained and qualified to conduct the Study.
- **c.** Obtain informed consent from all Study participants in accordance with applicable laws and regulations.
- **d.** Maintain accurate and complete Study records, including source documents, case report forms, and patient records.

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3. Principal Investigator

- **3.1** The Principal Investigator is responsible for the overall conduct of the Study at the Institution, ensuring compliance with the Protocol, GCP, and applicable regulatory requirements.
- **3.2** If the Principal Investigator is unable to continue leading the Study, the Institution shall promptly notify the Sponsor and identify a qualified replacement, subject to Sponsor's approval.

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4. Funding and Payments

- **4.1 Budget**: The Sponsor agrees to provide funding for the Study in accordance with the budget outlined in Exhibit B (the "Budget").
- **4.2 Payment Schedule**: Payments shall be made by the Sponsor to the Institution as follows:
  - **a.** [Amount] USD upon execution of this Agreement.
  - **b.** [Amount] USD upon the enrollment of [Number] Study participants.
  - **c.** [Amount] USD upon completion of the Study.
- **4.3 Payment for Services**: Payments are based on services rendered by the Institution in conducting the Study, including participant visits, data collection, and reporting.
- **4.4 Final Payment**: The final payment shall be made after the completion of all Study-related activities, including the submission of final reports and data to the Sponsor.

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5. Intellectual Property Rights

- **5.1 Ownership of Study Data**: All Study data, results, and intellectual property arising from the Study ("Study Data") shall be owned by the Sponsor.
- **5.2 Inventions**: Any inventions, discoveries, or improvements arising from the Study ("Inventions") shall be promptly disclosed to the Sponsor, and all rights to such Inventions shall belong to the Sponsor.
- **5.3 Institution's Use of Study Data**: The Institution may use the Study Data solely for non-commercial academic purposes, subject to prior written consent from the Sponsor.

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6. Confidentiality

- **6.1** Both parties agree to keep confidential any proprietary or confidential information disclosed by the other party during the Study, including Study Data, business information, and investigational products.
- **6.2** Confidential information shall not be disclosed to third parties without the prior written consent of the disclosing party, except as required by law.
- **6.3** Confidentiality obligations shall survive the termination or expiration of this Agreement for a period of [Number] years.

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7. Publication Rights

- **7.1** The Institution shall have the right to publish the results of the Study, subject to the following conditions:
    - **a.** The Institution shall provide the Sponsor with a copy of any proposed publication at least [Number] days prior to submission for publication.
    - **b.** The Sponsor shall have the right to review and comment on the proposed publication to ensure that confidential information and intellectual property are protected.
- **7.2 Delay of Publication**: The Sponsor may request a delay of up to [Number] months to file patent applications or protect intellectual property before the publication of Study results.

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8. Study Records and Audits

- **8.1 Study Records**: The Institution agrees to maintain complete and accurate Study records, including informed consent forms, case report forms, source documents, and any other documentation required by the Protocol or regulatory authorities.
- **8.2 Access to Records**: The Sponsor, regulatory authorities, and independent auditors shall have the right to inspect and audit the Study records upon reasonable notice and during regular business hours.
- **8.3 Record Retention**: The Institution shall retain all Study records for a period of at least [Number] years after the completion of the Study or longer if required by applicable regulations.

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9. Adverse Event Reporting

- **9.1** The Principal Investigator and Institution agree to promptly report any serious adverse events (SAEs) or adverse drug reactions (ADRs) to the Sponsor, as defined by the Protocol and regulatory requirements.
- **9.2** The Sponsor agrees to notify the appropriate regulatory authorities of any SAEs, if required.

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10. Indemnification and Liability

- **10.1 Sponsor's Indemnification**: The Sponsor agrees to indemnify and hold harmless the Institution, Principal Investigator, and their agents and employees from any claims, damages, or liabilities arising out of the Sponsor's negligence, the investigational product, or the conduct of the Study, except to the extent caused by the Institution's negligence or misconduct.
- **10.2 Institution's Indemnification**: The Institution agrees to indemnify and hold harmless the Sponsor from any claims, damages, or liabilities arising from the Institution's negligence, willful misconduct, or breach of this Agreement.
- **10.3 Insurance**: Each party agrees to maintain adequate insurance coverage to cover its respective liabilities under this Agreement.

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11. Term and Termination

- **11.1 Term**: This Agreement shall commence on the Effective Date and continue until the completion of the Study or until terminated as provided herein.
- **11.2 Termination for Convenience**: Either party may terminate this Agreement by providing [Number] days' written notice to the other party.
- **11.3 Termination for Breach**: Either party may terminate this Agreement for material breach by the other party, provided the breaching party fails to cure the breach within [Number] days after receiving written notice of the breach.
- **11.4 Effect of Termination**: Upon termination, the Institution shall cease all Study activities and return any unused investigational product to the Sponsor. The Sponsor shall compensate the Institution for services rendered up to the date of termination.

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12. Governing Law and Dispute Resolution

- **12.1 Governing Law**: This Agreement shall be governed by and construed in accordance with the laws of the State of **[State]**, without regard to its conflict of law principles.
- **12.2 Dispute Resolution**: Any disputes arising under or related to this Agreement shall first be submitted to mediation. If mediation is unsuccessful, the dispute shall be

resolved through binding arbitration in accordance with the rules of [Arbitration Organization] in [Jurisdiction].

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13. Miscellaneous Provisions

- **13.1 Entire Agreement**: This Agreement constitutes the entire agreement between the parties concerning the subject matter hereof and supersedes all prior agreements or understandings, whether written or oral.
- **13.2 Amendments**: Any amendments to this Agreement must be made in writing and signed by both parties.
- **13.3 Severability**: If any provision of this Agreement is found to be invalid or unenforceable, the remaining provisions shall remain in full force and effect.

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14. Signatures

By signing below, the parties acknowledge that they have read and fully understand the terms of this Clinical Trial Agreement and agree to be bound by them.

Sponsor

Signature: _____

Name: [Sponsor's Full Name]

Title: [Title]

Date: _____

Institution

Signature: _____

Name: [Institution's Representative]

Title: [Title]

Date: _____

Principal Investigator

Signature: _____

Name: [Principal Investigator's Full Name]

Date: _____

Disclaimer: This template is provided for informational purposes only and does not constitute legal advice. Clinical trial agreements can involve significant legal and regulatory obligations, and it is recommended to consult a qualified attorney to ensure that any agreement meets all legal requirements and addresses the specific needs of both parties.