CLINICAL TRIAL AGREEMENT

Between

CardioPharm International, Inc. ("Sponsor")
1500 Research Parkway
Cambridge, MA 02142

and

Memorial Medical Center ("Institution")
4400 University Drive
Cleveland, OH 44106

Effective Date: January 15, 2022

RECITALS

WHEREAS, Sponsor is developing an investigational cardiovascular therapeutic agent designated as CP-2847 ("Study Drug");

WHEREAS, Sponsor desires Institution to participate in a clinical study evaluating the Study Drug pursuant to Protocol No. CP-2847-301 ("Protocol");

WHEREAS, Institution operates a qualified clinical research facility and has Principal Investigator qualified to conduct the Study;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein, the parties agree as follows:

ARTICLE 1. DEFINITIONS

1.1 Protocol means Protocol No. CP-2847-301, "A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of CP-2847 in Patients with Hypertension and Left Ventricular Hypertrophy (HEARTBEAT-3)," Version 1.0 dated December 10, 2021, attached as Exhibit A.

1.2 Study means the clinical investigation described in the Protocol.

1.3 Study Drug means the investigational product CP-2847 and matching placebo supplied by Sponsor.

1.4 Principal Investigator or **PI** means Dr. Sarah Chen, MD, FACC, employed by Institution.

1.5 Study Data means all data, information, results, reports, and findings generated from the Study.

1.6 CRF means Case Report Form, whether electronic or paper-based.

1.7 IRB means the Institutional Review Board or Independent Ethics Committee.

ARTICLE 2. SCOPE OF WORK AND CONDUCT OF STUDY

2.1 Study Conduct. Institution and PI shall conduct the Study in accordance with: (a) the Protocol; (b) Good Clinical Practice standards as defined in ICH E6(R2); (c) applicable regulations including 21 CFR Parts 11, 50, 54, 56, and 312; (d) all applicable local, state, and federal laws; and (e) the terms of this Agreement.

2.2 Enrollment Target. Institution shall use commercially reasonable efforts to enroll **twenty (20) evaluable Study Subjects** over an estimated enrollment period of twelve (12) months commencing upon Site Activation.

2.3 Study Timeline. The Study is anticipated to be completed within eighteen (18) months from Site Activation, including a twelve (12) month enrollment period and six (6) month follow-up period.

ARTICLE 3. PRINCIPAL INVESTIGATOR QUALIFICATIONS AND OBLIGATIONS

3.1 PI Qualifications. The Principal Investigator represents and warrants that he/she:

(a) is qualified by training, education, and experience to assume responsibility for the proper conduct of the Study at the Site;

(b) holds a current, valid, and unrestricted medical license in the State of Ohio and is Board Certified in Cardiology;

(c) has not been debarred, disqualified, restricted, or sanctioned under Section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 335a);

(d) is not excluded from participation in any federal health care program; and

(e) shall promptly notify Sponsor in writing if any of the foregoing representations cease to be true.

3.2 FDA Form 1572. PI has executed FDA Form 1572 (Statement of Investigator) attached as Exhibit D.

3.3 Delegation of Authority. PI may delegate Study tasks to qualified sub-investigators and study staff, as documented in a Delegation of Authority Log, provided PI retains overall responsibility for Study conduct.

3.4 Adverse Event Reporting. PI shall report Serious Adverse Events (SAEs) to Sponsor within twenty-four (24) hours of becoming aware of the event.

ARTICLE 4. IRB/IEC APPROVAL AND REGULATORY COMPLIANCE

4.1 IRB Approval. Institution shall obtain and maintain IRB approval for the Protocol and Informed Consent Form prior to enrolling any Study Subjects.

4.2 HIPAA Compliance. Institution shall comply with the Health Insurance Portability and Accountability Act (HIPAA) and shall obtain appropriate HIPAA authorizations from Study Subjects.

4.3 ClinicalTrials.gov. Sponsor shall register the Study on ClinicalTrials.gov as required by 42 CFR Part 11.

ARTICLE 5. INFORMED CONSENT

5.1 Informed Consent Process. Institution and PI shall obtain voluntary written informed consent from each Study Subject prior to performing any study-specific procedures, using the ICF approved by the IRB and attached as Exhibit C.

5.2 Consent Documentation. Institution shall maintain signed ICFs in Study records and provide copies to Study Subjects.

ARTICLE 6. STUDY DRUG

6.1 Supply. Sponsor shall supply Study Drug in sufficient quantities to conduct the Study at no cost to Institution or Study Subjects.

6.2 Accountability. Institution shall maintain accurate records of Study Drug receipt, dispensing, return, and destruction.

6.3 Storage. Institution shall store Study Drug under conditions specified in the Pharmacy Manual at 2-8°C with temperature monitoring.

ARTICLE 7. COMPENSATION AND PAYMENT

7.1 Budget. Sponsor shall compensate Institution according to the Budget attached as Exhibit B. All payments represent Fair Market Value for services rendered and are not intended to induce referrals in violation of the Anti-Kickback Statute (42 U.S.C. § 1320a-7b).

7.2 Payment Terms. Institution shall submit invoices monthly. Sponsor shall pay undisputed invoices within thirty (30) days of receipt ("Net 30").

7.3 Milestone Payments. Specific milestone payments are detailed in Exhibit B and include:

- Site Startup Payment: Upon IRB approval and Site Activation
- Per-Patient Payments: Upon completion of study visits per enrolled Subject
- Screen Failure Payment: For subjects who sign consent but fail screening
- Site Closeout Payment: Upon completion of closeout visit and final data queries

7.4 Holdback. Sponsor shall withhold ten percent (10%) of each per-patient payment as a retention amount. The retained amount shall be released within sixty (60) days of the later of: (a) Last Patient Last Visit at the Site; (b) resolution of all outstanding data queries; and (c) completion of the Site Close-Out Visit.

7.5 Pass-Through Costs. Institution may invoice for pre-approved pass-through costs (laboratory, imaging, ECG) at actual cost incurred, with supporting documentation.

ARTICLE 8. CONFIDENTIALITY

8.1 Confidential Information. Each party agrees to maintain in confidence all Confidential Information disclosed by the other party, defined as all non-public information relating to the Study, Study Drug, Study Data, and business operations.

8.2 Exclusions. Confidential Information does not include information that: (a) is publicly available through no breach of this Agreement; (b) was rightfully known prior to disclosure; (c) is independently developed; or (d) is received from a third party with no duty of confidentiality.

8.3 Duration. Confidentiality obligations shall survive for seven (7) years following termination or completion of this Agreement.

ARTICLE 9. DATA OWNERSHIP, COLLECTION, AND RETENTION

9.1 Data Ownership. All Study Data is the sole and exclusive property of Sponsor.

9.2 Data Retention. Institution shall retain all Study Data and records for **fifteen (15) years** from completion or termination of the Study, or such longer period as required by applicable laws.

9.3 Data Integrity. Institution shall ensure Study Data meets ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, complete, consistent, enduring, available).

9.4 Record Access. Institution shall provide Sponsor, regulatory authorities, and IRB access to all Study records upon reasonable notice.

ARTICLE 10. PUBLICATION RIGHTS

10.1 PI Publication Rights. PI and Institution have the right to publish or present Study results, subject to the following conditions:

10.2 Sponsor Review. PI shall provide Sponsor with manuscripts at least sixty (60) days prior to submission for publication, and abstracts at least thirty (30) days prior to submission.

10.3 Sponsor Delay Rights. Sponsor may request up to an additional sixty (60) days delay for patent filing purposes.

10.4 Confidential Information. PI shall remove any Sponsor Confidential Information identified by Sponsor from proposed publications.

ARTICLE 11. INTELLECTUAL PROPERTY

11.1 Background IP. Each party retains all right, title, and interest in its Background Intellectual Property existing prior to this Agreement.

11.2 Study Inventions. All inventions, discoveries, or improvements arising from the Study shall be the sole property of Sponsor.

11.3 Bayh-Dole. To the extent any Study inventions constitute Subject Inventions under the Bayh-Dole Act (35 U.S.C. § 200 et seq.) due to federal funding, Institution retains rights as provided under that Act.

ARTICLE 12. INDEMNIFICATION

12.1 Sponsor Indemnification. Sponsor shall indemnify, defend, and hold harmless Institution, its trustees, officers, agents, employees, and the Principal Investigator (collectively, "Indemnitees") from and against any and all claims, damages, losses, costs, and expenses (collectively, "Losses") arising out of or resulting from:

(a) the use, manufacture, or distribution of the Study Drug;

(b) Sponsor's negligence or willful misconduct; or

(c) the design of the Protocol;

to the extent such Losses do not arise from: (i) the negligence or willful misconduct of any Indemnitee; (ii) failure to comply with the Protocol; or (iii) failure to obtain valid informed consent.

12.2 Institution Indemnification. Institution shall indemnify, defend, and hold harmless Sponsor from Losses arising from Institution's or PI's negligence, willful misconduct, or material breach of this Agreement.

12.3 Indemnification Procedures. The indemnified party shall promptly notify the indemnifying party of any claim, cooperate in defense, and permit the indemnifying party to control defense and settlement.

ARTICLE 13. INSURANCE

13.1 Clinical Trial Insurance. Sponsor represents that it maintains clinical trial liability insurance with

minimum coverage of One Million Dollars ($1,000,000) per occurrence and Three Million Dollars ($3,000,000) aggregate.

13.2 Professional Liability Insurance. Institution represents that it maintains professional liability insurance covering PI and study staff with minimum coverage of One Million Dollars ($1,000,000) per occurrence and Three Million Dollars ($3,000,000) aggregate.

13.3 Certificates of Insurance. Each party shall provide the other with certificates of insurance upon request, attached as Exhibit G.

13.4 Insurance Duration. Insurance coverage shall remain in effect for the duration of the Study and for a period of three (3) years following Study completion.

ARTICLE 14. SUBJECT INJURY AND MEDICAL CARE

14.1 Study-Related Injury. Sponsor shall be responsible for costs of medical care for Study-Related Injuries, defined as injuries directly caused by Study Drug or required Study procedures, excluding injuries resulting from underlying disease progression or standard-of-care treatment.

14.2 Emergency Medical Care. Institution shall provide or arrange for emergency medical care for Study Subjects as medically necessary.

ARTICLE 15. MONITORING, AUDITS, AND INSPECTIONS

15.1 Sponsor Monitoring. Sponsor or its designees may monitor Study conduct and inspect Study records at reasonable times with reasonable advance notice.

15.2 Regulatory Inspections. Institution shall cooperate with inspections by FDA, EMA, or other regulatory authorities and shall promptly notify Sponsor of any inspection notice.

ARTICLE 16. TERM AND TERMINATION

16.1 Term. This Agreement is effective as of the Effective Date and shall continue until completion of all obligations hereunder, anticipated to be December 31, 2024, unless earlier terminated.

16.2 Termination for Cause. Either party may terminate this Agreement for material breach upon thirty (30) days written notice if the breach remains uncured.

16.3 Termination for Convenience. Either party may terminate this Agreement for any reason upon sixty (60) days written notice.

16.4 Immediate Termination. Sponsor may terminate immediately upon: (a) disqualification or debarment of PI; (b) loss of IRB approval; (c) safety concerns; or (d) regulatory hold.

16.5 Effect of Termination. Upon termination, Institution shall: (a) cease enrollment; (b) complete follow-up for enrolled subjects if medically appropriate; (c) return all Study Drug; (d) provide all Study Data to Sponsor; and (e) submit final invoice.

ARTICLE 17. REPRESENTATIONS AND WARRANTIES

17.1 Debarment Certification. Each party represents that it has not been debarred under 21 U.S.C. § 335a and shall notify the other party immediately if debarred.

17.2 Authority. Each party represents that it has full authority to enter into this Agreement and that execution has been duly authorized.

17.3 Compliance. Each party shall comply with all applicable laws, regulations, and ethical standards.

ARTICLE 18. INDEPENDENT CONTRACTOR

18.1 Relationship. Institution and PI are independent contractors. Nothing herein creates an employment,

agency, partnership, or joint venture relationship.

ARTICLE 19. ASSIGNMENT

19.1 No Assignment. Neither party may assign this Agreement without the prior written consent of the other party, except Sponsor may assign to an affiliate or in connection with a merger or acquisition.

ARTICLE 20. DISPUTE RESOLUTION

20.1 Negotiation. The parties shall attempt to resolve disputes through good faith negotiation for thirty (30) days.

20.2 Mediation. If negotiation fails, disputes shall be submitted to non-binding mediation in Cleveland, Ohio.

20.3 Litigation. If mediation fails, disputes shall be resolved in the state or federal courts located in Cuyahoga County, Ohio.

ARTICLE 21. GENERAL PROVISIONS

21.1 Entire Agreement. This Agreement, including all Exhibits, constitutes the entire agreement between the parties and supersedes all prior agreements.

21.2 Amendments. This Agreement may be amended only by written instrument signed by both parties.

21.3 Severability. If any provision is held invalid, the remaining provisions shall remain in full force and effect.

21.4 Waiver. No waiver of any provision shall constitute a waiver of any other provision or subsequent breach.

21.5 Survival. Articles 8 (Confidentiality), 9 (Data Retention), 10 (Publication), 11 (IP), 12 (Indemnification), and 20 (Dispute Resolution) shall survive termination.

21.6 Notices. All notices shall be in writing and sent to the addresses on the signature page.

21.7 Force Majeure. Neither party shall be liable for delay or failure in performance caused by circumstances beyond such party's reasonable control, including acts of God, fire, flood, earthquake, or war.

21.8 Governing Law. This Agreement shall be governed by the laws of the State of Ohio, without regard to conflict of law principles.

21.9 Order of Precedence. In the event of conflict, the following order of precedence applies: (1) this Agreement; (2) Protocol; (3) Exhibits.

SIGNATURES

CARDIOPHAM INTERNATIONAL, INC.

By: _____
Name: Michael Rodriguez
Title: VP, Clinical Operations
Date: January 15, 2022

MEMORIAL MEDICAL CENTER

By: _____
Name: Dr. Patricia Williams
Title: Director, Clinical Research Office
Date: January 15, 2022

EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

Study: HEARTBEAT-3 (Protocol CP-2847-301)
Site: Memorial Medical Center
PI: Dr. Sarah Chen
Enrollment Target: 20 patients
Budget Version: 1.0
Date: January 15, 2022

SITE STARTUP COSTS

Item	Amount
IRB Submission & Approval	$3,500
Regulatory Document Preparation	$2,000
Site Initiation Visit	$4,000
Site Activation Payment	$5,000
TOTAL STARTUP	**$14,500**

PER-PATIENT COSTS

Target Enrollment: 20 patients
Per-Patient Total: $18,500

Visit	Procedures	Payment per Patient
Screening	Consent, vitals, ECG, echo, labs, medical history	$2,200
Baseline/Randomization	Vitals, ECG, labs, drug dispensing	$1,100
Week 4	Vitals, ECG, labs, drug dispensing	$900
Week 8	Vitals, ECG, labs, drug dispensing	$900
Week 12	Vitals, ECG, echo, labs, drug dispensing	$1,600
Week 16	Vitals, ECG, labs, drug dispensing	$900
Week 20	Vitals, ECG, labs, drug dispensing	$900
Week 24	Vitals, ECG, echo, labs, drug dispensing	$1,600
Week 28	Vitals, ECG, labs, drug dispensing	$900
Week 32	Vitals, ECG, labs, drug dispensing	$900
Week 36	Vitals, ECG, echo, labs, drug dispensing	$1,600
Week 40	Vitals, ECG, labs, drug dispensing	$900
Week 44	Vitals, ECG, labs, drug dispensing	$900
Week 48 (End of Treatment)	Vitals, ECG, echo, labs, safety follow-up	$1,600
Week 52 (Follow-up)	Vitals, ECG, labs, safety follow-up	$800
TOTAL PER PATIENT		**$18,500**

Total for 20 Patients: $370,000

SCREEN FAILURE PAYMENT

Per Screen Failure: $1,200 (for subjects who consent but fail screening)

Estimated Screen Failures (30% rate): 8 patients
Estimated Screen Failure Total: $9,600

SITE CLOSEOUT

Item	Amount
Close-Out Visit	$3,000
Final Query Resolution	$1,500
Drug Accountability & Return	$500
Document Archival	$1,000
TOTAL CLOSEOUT	**$6,000**

PASS-THROUGH COSTS

Institution may invoice for the following at actual cost with documentation:

- Central laboratory costs (pre-approved vendor)
- ECG reading fees (central ECG lab)
- Echocardiogram reading fees (core lab)
- Unscheduled visits required for safety monitoring

Estimated Pass-Through Costs: $8,000

TOTAL SITE BUDGET

Category	Amount
Site Startup	$14,500
Per-Patient Costs (20 patients)	$370,000
Screen Failures (estimated 8)	$9,600
Site Closeout	$6,000
Pass-Through Costs (estimated)	$8,000
TOTAL BUDGET	**$408,100**

PAYMENT TERMS

- **Holdback:** 10% of per-patient payments retained until LPLV + query resolution + closeout
- **Payment Schedule:** Net 30 from invoice receipt
- **Invoicing:** Monthly invoicing permitted for completed visits
- **Holdback Release:** Within 60 days of closeout completion