CorMedix Therapeutics

Investigator-Initiated Research (IIR) and External Research Collaboration (ERC) Concept Submission

Complete this form to submit an IIR or ERC concept to CorMedix Therapeutics for consideration by its Grants Review Committee (GRC). Note there are two research categories – Investigator-Initiated Research (IIR) and External Research Collaboration (ERC). Please see the definitions of these study types below.

Investigator-Initiated Research (IIR) includes clinical trials, registries, or other forms of research (e.g., real-world evidence studies, health outcomes research studies, or pre-clinical research) proposed and conducted by a third-party investigator, who assumes all responsibility for the study and serves as the regulatory sponsor-investigator. Medical personnel at CorMedix may not collaborate scientifically with the investigator(s) on an IIR study.

External Research Collaboration (ERC) includes clinical trials, registries, or other forms of research (e.g., real-world evidence studies, health outcomes research studies, or pre-clinical research) where a third-party investigator proposes the study, or CorMedix solicits a research proposal from appropriate, qualified investigators. The investigator serves as the regulatory sponsor-investigator and assumes all responsibility for the conduct of the study. Medical personnel at CorMedix may collaborate scientifically with the investigator, including providing input on the study design, analyzing data and results, and authoring the study report or related publications.

For both IIRs and ERCs, CorMedix may provide drug, financial support, or both. These studies can involve investigational or marketed products.

Principal Investigator (PI) Contact Information	
Name	
Title	
Institution/Organization	
Office font Address Phone Email	
List all co-investigators (names, titles, institution/organization)	
Name and contact information of the person submitting this form, if not the PI	

389 Interpace Parkway, Suite 450, Parsippany, NJ 07054
www.cormedix.com

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Study Specifications		
Title of Proposal		
CorMedix Drug to be Studied		
Study Type (select one; refer to definitions below)	☐ Investigator Initiated Research (IIR) ☐ External Research Collaboration (ERC)	
Study Design (check all that apply)	☐ In vitro (see Active Pharmaceutical Ingredient (API) request) ☐ Animal (see API request) ☐ Retrospective, clinical ☐ Prospective, clinical ☐ Case series ☐ Pharmacokinetic/Pharmacodynamic	If 'Other', please specify:
Patient Population (if applicable) to be Studied (e.g., disease state, pathogen, subpopulation)		
Sample Size	Number of patients to be evaluated across all arms/cohorts (if applicable): _____ Comparator drug(s) (if applicable; state drug name and no. of patients for each:	
Will the institution engage any external sites, hospitals, or clinics in the conduct of this study or in providing data for this study? If so, please list institution names, if available.		

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Deliverables and Timelines for Research	
Publication Plan	Please describe the planned publications (including scientific meeting abstracts/posters and manuscripts) that you intend to submit. Please include timing and target scientific meeting or journal.
Timeline for Study Completion	

Regulatory & Institutional Review Board/Committee Review Process (IRB, EC, etc.)	
Board/Committee Review	What type of approval will be required for this study? ☐ IRB ☐ Ethics Committee ☐ IACUC ☐ Other:
	What is the date of the next review board/committee meeting? How often does this board/committee meet (e.g. monthly)?
Anticipated Regulatory Status	Regulatory Status (if known): ☐ IND anticipated ☐ IND-exempt anticipated ☐ Not yet determined If known, please briefly describe the anticipated regulatory status. Final determination and responsibility for IND submission (if required) rests with the investigator as sponsor-investigator.
Other comments related to approval requirements	

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Type of Support Requested	
Budget Requested	Are funds being requested from CorMedix for this request? ☐ NO ☐ YES* If Yes, total amount requested: _____ *If 'YES', please attach an itemized and detailed budget showing the breakdown of costs. Provide a date for the budget.
	Please confirm if funding or materials have been or will be requested from other manufacturers or grant sources (e.g., university, NIH, other) and the amount:
Study Drug Supply (API powder or commercially available drug vials for human use)	In vitro/In vivo, animal studies: If this proposal requires API, please provide the amount of powder requested. Drug: _____ Amount (milligrams): _____
	Clinical (human) studies: If drug vials for human use are being requested, provide the drug name, vial dose size and number of vials: (in the Proposal, provide calculation for the number of vials requested) Drug: _____ Vial size (milligrams/grams): _____ Number of single-use vials needed: _____
If the study requires other support from CorMedix, please define here and include in the proposal	

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Clinical Study Proposal
Please attach a brief study rationale and study synopsis, including the central hypotheses, specific aims of the study, and expected outcomes and impact of the anticipated results.

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