ACCORD BIOPHARMA
LOI FOR SCHEMA PROTOCOL
Letter of Intent Template

Before an investigator writes an institutional protocol for an interventional study, it is highly recommended they submit a Letter of Intent (LOI) to the Accord's IIR Review Committee (IRC) for approval prior to completing an extensive IIR application. An LOI is not required for a chart review or lab-based study. This letter should *briefly* address all of the following points. Use additional pages if necessary. Submit a completed LOI electronically to the ACCORD BIOPHARMA website or medical affairs representative. A complete Contract Research Organization (CRO) submission of your protocol. (If your LOI is approved, the complete submission will come later).

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1. Principal Investigator:

2. Multi-Center Trial: ☐ **Yes** ☐ **No**

Anticipated Participating Sites (please list all):

3. CONCEPT INFORMATION	
Concept Title:	
Primary Objective:	
Secondary Objective(s):	
Study Phase:	☐ I ☐ I/II ☐ II ☐ III ☐ IV ☐ Pilot ☐ N/A

4. CONCEPT DESIGN AND RATIONALE	
a)	***Background Information on Disease State and Treatment Rationale*** *Include supporting preliminary data, either multicenter experience or correlative science studies integral to the study. Include limitations of existing therapeutic options.*

For IRC Administrative Use Only

Date of IRC Approval: / /

Date Letter Sent to PI: / /