ACCORD BIOPHARMA
LOI FOR INVESTIGATOR INITIATED RESEARCH (IIR)
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. Before the LOI is presented to the IRC, the IRC Coordinator will obtain the approval of the Disease Section Leader via email. 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.*

b)	***Type of Study Design:*** ***Allocation:*** ☐ **Randomized** ☐ **Non Randomized** ☐ **N/A: Single-arm study** ***Intervention Model*:** ☐ **Single Group:** single arm study ☐ **Parallel:** participants are assigned to one of two or more groups in parallel for the duration of the study ☐ **Cross-over:** participants receive one of two alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study ☐ **Factorial:** two or more interventions, each alone and in combination, are evaluated in parallel against a control group
c)	***Scientific Rationale for Dosing Schema*** *(For all drugs in regimen, if dose is not by product/package insert, provide rationale below.)*

5. STUDY POPULATION	
a) Diagnosis or Disease being Studied:	
b) Key Inclusion Criteria:	**1.** **2.** **3.** **4.** **5.**
c) Key Exclusion Criteria:	**1.** **2.** **3.** **4.** **5.**

6. CORRELATIVE STUDIES (Pharmacogenomics)	
Correlative studies to be performed:	
Where will correlative studies be done?	☐ At all Sites ☐ Other, Specify:
List the time points of sample collection and the estimated total number of samples:	
How will samples be processed?	☐ Private Clinical Facility ☐ Sponsor ☐ Other, specify:
Time Period	Do you anticipate samples will be collected over more than an 8 hour time period? ☐ Yes ☐ No If yes, Clinical Research Unit (CRU) services may need to be used for the study.

7. TREATMENT DETAILS				
Treatment:				
DRUG	***DOSE***	***FREQUENCY***	***# OF CYCLES***	***ROUTE OF ADMINISTRATION***

Arm/Cohort 1:				
Arm/Cohort 2:				
Arm/Cohort 3:				
Arm/Cohort 4:				

8. STATISTICS	
Statistical Considerations:	
Proposed sample size:	

9. FEASIBILITY ASSESSMENT	
Accrual Projections:	Eligible number of patients per month seen: Projected accrual rate / Patients per month: Are there any protocols that would compete with patient accrual? ☐ No ☐ Yes (*specify)*

10. TYPE OF SUPPORT	
Type of Support:	☐ Drug ☐ Financial
Will other support be provided by other Pharm/Biotech Companies:	☐ No ☐ Yes (*specify)*

11. Investigational New Drug (IND) DETERMINATION

Will this study require filing for an IND (US studies only): ☐ Yes ☐ No

Study meets the below criteria for IND exemption status (21CFR 312.2 (b)(1)(l)-(v): *(for US studies only)*

☐ Yes ☐ No

I. The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;

II. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;

III. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increased the risk (or decreases the acceptability of the risks) associated with the use of the drug product;

IV. The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in Part 50; and

V. The investigation is conducted in compliance with the requirements of § 312.7.

12. PUBLICATION PLAN

All cancer relevant studies conducted are expected to follow clinicaltrials.gov registration laws as specified by US Public Law 110-85, Title VIII, Section 801 (http://prsinfo.clinicaltrials.gov/fdaaa.html)

Studies who use CRO regulatory services will follow ICMJE requirements (http://www.icmje.org) for disclosure of protocol and results information to www.clinicaltrials.gov.	
Target Abstract Submission(s)	
Target Venue: *(specify meeting, journal):*	
Target Venue Date *(mm/dd/yyyy):*	
Intend to submit final manuscript to a peer-reviewed journal	☐ Yes ☐ No

For IRC Administrative Use Only

Date of IRC Approval: / /

Date Letter Sent to PI: / /