Baudax BIO®

ISR Concept Submission Template:

Unsolicited Clinical Concept* Submitted for
Review by the Baudax Bio Grant Review Committee (GRC).

Completion of this form is required as the first step in the Investigator Sponsored Research (ISR) program as outlined by Baudax Bio. Please reference our corporate website for a full overview of related guidelines and FDA guidance related to ISRs.

By completing, and subsequently submitting, this form, the potential Grant Recipient requests Baudax Bio support of Investigator Sponsored Research.

**Submission of this ISR Concept Submission Template must not be solicited by Baudax Bio.*

Submit this COMPLETED form via the Baudax Bio ISR webpage at:
https://www.baudaxbio.com/rd/investigator-sponsored-research/submission-form

Response Timing: Upon receipt, your ISR Concept Submission documents will be reviewed thoroughly by the Baudax Bio Grant Review Committee (GRC) in accordance with Baudax Bio's ISR Policy. Please allow 7-10 business days for Baudax Bio to acknowledge receipt of your submission. Incomplete/incorrect information within this form may delay review of your submission.

IMPORTANT: The Baudax Bio GRC provides no guarantee that any single proposal will receive support.

Primary Investigator Information

Date of Submission	
Name & Title	
Department	
Institution	
Primary Degree	
Institution of Primary Degree	
Secondary Degree	
Institution(s) of Secondary Degree	
License Number(s) *If not applicable, please leave blank*	
State(s) of Licensure *If not applicable, please leave blank*	
Address	
Telephone Number	
Fax Number	
Email Address	
Preferred Method of Contact	

Clinical Site Information

Organization/Institution	
Major Therapeutic Area of Interest/Specialty	
Clinical Trial Experience?	
Experience With ISRs?	
Existing Support Staff to Conduct ISRs?	
Please List the Name(s) and Title(s) of All Support Staff	
Support Staff With Biostats Data Management Experience?	
Current Ongoing Clinical Trial(s) at This Site?	

Sub-Investigator Information

Name & Title	
Department	
Institution	
Primary Degree	
Institution of Primary Degree	
Secondary Degree	
Institution(s) of Secondary Degree	
License Number(s) *If not applicable, please leave blank*	
State(s) of Licensure *If not applicable, please leave blank*	
Address	
Telephone Number	
Fax Number	
Email Address	
Preferred Method of Contact	

Research Coordinator/Main Point of Contact (if different from above)	
Name & Title	
Department	
Address	
Telephone Number	
Fax Number	
Email Address	
Preferred Method of Contact	

Concept Overview

If any of the following fields do not apply to your proposed study, please leave blank.

Study Title	
Rationale/Description *A full overview of rationale related to your unsolicited request.* *Include necessary References in this section.*	
Hypothesis	
Objective(s)	
Phase	

Concept Overview (con't)

If any of the following fields do not apply to your proposed study, please leave blank.

IND Exempt or IND Submission Planned	
Study Design/Type	
Target Population	
Source of Target Research Subjects *(existing patients, recruitment, etc.)*	
Sample Size (*N*)	
Number of Potential Subjects Meeting Research Criteria Seen per Month	
Treatment Regimen *Provide multimodal analgesia protocol or other proposed protocol*	
Treatment Duration	
Primary Endpoints	
Key Secondary Endpoints	

Concept Overview (con't)

If any of the following fields do not apply to your proposed study, please leave blank.

Major Eligibility Criteria	*Inclusion criteria:* *Exclusion criteria:*
Number of Sites Participating	
Site Location(s) *(if multiple)*	
Brief Description of Planned Statistical Analysis	
Validated Metrics, Scales, and/or Questionnaires of Interest	

Timelines (High-Level)

Anticipated Start Date *(if approved)*	
Final Protocol	
IRB Approval	
First Patient In	
Last Patient Out	
Final Report/Publication	

Investigational Medicinal Product (IMP) Requested

Shipment of IMP is governed under BAUDAX SOP 50-009

Name of Product Requested *Mark all that apply*	☐ *Meloxicam IV 30 mg/mL vial* ☐ *Other:*
Dosage Strength	☐ *Other:*
Estimated Quantity per Subject	
Total Number of Subjects (*N*)	
Estimated Total Product Required	
Distribution Vendor *(if study has multiple sites)*	

Additional Information (Required)

Do you know/are you aware of any other research groups working on the same or related studies?

Have you worked with Baudax Bio in the past? If so, please explain.

Have you worked with Recro Pharmaceuticals in the past? If so, please explain.

Please list any complete and pending FDA or state inspections related to your Clinical Site.

Additional Information (Required)

Please provide a history of FDA inspections and 483s.

Have you, or anyone else who will participate in this study, been disqualified or debarred by any governmental agency or are currently the subject of an investigation or inquiry by the government or your employer? If so, please explain.

Does your facility have adequate locked storage area for drug? If so, please explain.

Please provide ANY additional information that you feel is important for the review of your ISR Concept Submission form by the Baudax Bio GRC.

Publication Plan

Please provide an overview of your Public Disclosure Plan (PDP) including details around publications and postings to a worldwide public register for all human subject research (e.g., https://clinicaltrials.gov/)

Please note, ISR Publication Guidance is available on the Baudax Bio corporate website.

What publication is planned (mark all that apply):

☐ **Abstract** *(if so, to what scientific meeting(s)/congress(es) will the abstract be submitted and when will it/they be held?)*

☐ **Manuscript** *(if so, what are the target journal and target publication date?)*

☐ **Study report** *(if so, what is the planned date of completion?)*

☐ **Other** *(please specify)*

☐ **No publication will be generated** *(if so, why not?)*

Project Budget (in USD)

Requested Support	
Duration of Support	
Institutional Funding	
Other Support *(e.g., foundation funding)*	
Estimated Budget	
Personnel*:	
Facilities:	
Supplies:	
Other (specify):	
Total Project Expenses	

**Compensation should reflect Fair Market Value*

Additional Documentation to Include in Online Submission (Required)

Please attach the following documents to your online submission:

- **ISR Concept Submission Template**
- **CV with a list of publications**

Please sign and complete this form on the following page.

Certifications

Potential Grant Recipients are required to agree to the following certifications:

- You are currently an employee of the requesting organization and you have the authority to apply for support from Baudax Bio
- Baudax Bio has no involvement in the development or execution of this study
- The source of support from Baudax Bio or other commercial entity will be disclosed in all publications and presentations
- You, your organization, and all study participants will comply with all applicable Global Trade Control Laws
- You are responsible for complying with all applicable requirements under the investigational new drug (IND) regulations at 21 CFR Part 312
- You are also responsible for complying with all applicable human subjects research requirements under 45 CFR 46 and FDA's implementing regulations under 21 CFR Parts 50 and 56
- You are also responsible for complying with FDA's regulations regarding financial disclosure by clinical investigators under 21 CFR Part 54

Signature(s) Required

Signature (Potential Grant Recipient) Date

If the potential Grant Recipient is an employee of an Institution and does not have the authority to sign for the Institution, please have document co-signed by an authority of the Institution.

Printed Name (Institutional Authority)

Signature (Institutional Authority) Date

If you have any questions or concerns related to the submission of your Unsolicited Investigator Sponsored Research Proposal, please reach out to the email address listed below. Additionally, all completed submissions should be submitted via the Baudax Bio ISR webpage at https://www.baudaxbio.com/rd/investigator-sponsored-research/submission-form.

Inquiry Email Address: ISRSupport@baudaxbio.com

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***Any approvals, consents or oral agreements by Baudax Bio, Inc. have no legal or other binding effect unless and until a separate written legal agreement is executed by the parties covering the study. Notwithstanding any such agreement, Baudax Bio, Inc. reserves the right to terminate any support or involvement in the study at any time whatsoever, subject to its sole discretion.*

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