

[Your Name]

[Your Position/Title]

[Institution Name]

[Address]

[Email Address]

[Phone Number]

[Date]

The Chairperson

Institutional Ethics Committee

[Institution/Hospital Name]

[Address]

Subject: Ethics Committee Submission for the Study Titled

"Efficacy, Safety and Tolerability of Tofacitinib for Treatment of Polyarticular Course Juvenile Idiopathic Arthritis (JIA) in Children and Adolescent Subjects"

Dear Sir/Madam,

I am pleased to submit, for your kind review and approval, the protocol and related documents for the above-mentioned clinical study. The study is designed to evaluate the efficacy, safety, and tolerability of Tofacitinib in the treatment of polyarticular course Juvenile Idiopathic Arthritis (JIA) in children and adolescents.

This study aims to address the unmet therapeutic need in this vulnerable population by exploring an oral targeted therapy that may offer significant clinical benefit. The study will be conducted in

compliance with the ICH-GCP guidelines, applicable regulatory requirements, and institutional ethical standards.

Please find enclosed the following documents for your review:

- Study Protocol
- Informed Consent and Assent Forms
- Investigator's Brochure
- Case Report Forms (if applicable)
- CV of the Principal Investigator
- Site Feasibility Questionnaire (if applicable)
- Other required documents as per the IEC submission checklist

We assure you that participant safety and ethical conduct will be of utmost priority throughout the study. We respectfully request your review and approval of this submission at your earliest convenience.

Thank you for your time and consideration. Please feel free to contact me for any further information or clarification.

Yours sincerely,

[Your Full Name]

[Designation, Department]

[Institution Name]