

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration INVESTIGATIONAL NEW DRUG APPLICATION (IND) (Title 21, Code of Federal Regulations (CFR) Part 312)		Form Approved: OMB No. 0910-0014 Expiration Date: September 30, 2026 See PRA Statement on page 3. NOTE: No drug/biologic may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40)	
1. Center (select one) ☐ CDER ☐ CBER		2. Name of Sponsor	
3. Date of Submission (mm/dd/yyyy)			
4. Sponsor Address		5. Telephone Number (Include country code if applicable and area code)	
Address 1 (Street address, P.O. box, company name c/o)			
Address 2 (Apartment, suite, unit, building, floor, etc.)			
City		7A. IND Number (If previously assigned)	
State/Province/Region			
Country		7B. IND Type (select one) ☐ Commercial ☐ Research	
ZIP or Postal Code			
6. Name of Drug (Include all available names: Trade, Generic, Chemical, or Code)			
8A. (Proposed) Indication for Use		Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ No	
Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ No		If yes, provide the Orphan Designation number for this indication:	
8B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term)			
9. Phase of Clinical Investigation to be conducted ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Other (Specify): _____			
10. List numbers of all Investigational New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314), Drug Master Files (21 CFR Part 314.420), and Biologics License Applications (21 CFR Part 601) referred to in this application.			
11. IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The Serial Number next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted..			
12A. This submission contains the following (Select all that apply)			
☐ Initial Investigational New Drug Application (IND) ☐ Response to Clinical Hold ☐ Response To FDA Request For Information			
☐ Request For Reactivation Or Reinstatement ☐ Annual Report ☐ General Correspondence			
☐ Development Safety Update Report (DSUR) ☐ Other (Specify): _____			
Protocol Amendment Information Amendment Request for IND Safety Report ☐ New Protocol ☐ Chemistry/Microbiology ☐ Meeting ☐ Initial Written Report ☐ Change in Protocol ☐ Pharmacology/Toxicology ☐ Proprietary Name Review ☐ Follow-up to a Written Report ☐ New Investigator ☐ Clinical/Safety ☐ Special Protocol Assessment ☐ PMR/PMC Protocol ☐ Statistics ☐ Formal Dispute Resolution ☐ HF Validation Protocol ☐ Clinical Pharmacology ☐ Use-Related Risk Analysis			
12B. Does the submission contain: Digital Health Technology (DHT) data or a proposal to collect DHT data? ☐ Yes ☐ No		13. For Originals, is the product a combination product (21 CFR 3.2(e))? ☐ Yes ☐ No	
		Combination Product Type (See instructions)	
		Request for Designation (RFD) Number	
For FDA Use Only			
CBER/DCC Receipt Stamp		DDR Receipt Stamp	
		Division Assignment	
		IND Number Assigned	

14. Select the following only if applicable. (<i>Justification statement must be submitted with application for any items selected below. Refer to the cited CFR section for further information.</i>)				
☐ Emergency Research Exception From Informed Consent Requirements, 21 CFR 312.23 (f) ☐ Charge Request, 21 CFR 312.8		<i>Expanded Access Use, 21 CFR 312.300</i>		
		☐ Individual Patient, Non-Emergency 21 CFR 312.310 ☐ Individual Patient, Emergency 21 CFR 312.310(d) ☐ Intermediate Size Patient Population, 21 CFR 312.315 ☐ Treatment IND or Protocol, 21 CFR 312.320		
15. Contents of Application – This application contains the following items (<i>Select all that apply</i>)				
☐ 1. Form FDA 1571 (21 CFR 312.23(a)(1)) ☐ 2. Table of Contents (21 CFR 312.23(a)(2)) ☐ 3. Introductory statement (21 CFR 312.23(a)(3)) ☐ 4. General Investigational plan (21 CFR 312.23(a)(3)) ☐ 5. Investigator's brochure (21 CFR 312.23(a)(5)) ☐ 6. Protocol (21 CFR 312.23(a)(6)) ☐ a. Study protocol (21 CFR 312.23(a)(6)) ☐ b. Investigator data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572 ☐ c. Facilities data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572		6. Protocol (<i>Continued</i>) ☐ d. Institutional Review Board data (21 CFR 312.23(a)(6)(iii) (b)) or completed Form FDA 1572 ☐ 7. Chemistry, manufacturing, and control data (21 CFR 312.23(a)(7)) ☐ Environmental assessment or claim for exclusion (21 CFR 312.23(a)(7)(iv)(e)) ☐ 8. Pharmacology and toxicology data (21 CFR 312.23(a)(8)) ☐ 9. Previous human experience (21 CFR 312.23(a)(9)) ☐ 10. Additional information (21 CFR 312.23(a)(10)) ☐ 11. Biosimilar User Fee Cover Sheet (<i>Form FDA 3792</i>) ☐ 12. Clinical Trials Certification of Compliance (<i>Form FDA 3674</i>)		
16. Is any part of the clinical study to be conducted by a contract research organization? (21 CFR 312.52) ☐ Yes ☐ No If yes, use the Continuation Page to provide a statement containing the name and address of the CRO, identification of the clinical study and a listing of the obligations transferred (21 CFR 312.23(a)(1)(viii) and 21 CFR 312.52).				
17. Name and Title of the person responsible for monitoring the conduct and progress of the clinical investigations				
18. Name and Title of the person responsible for review and evaluation of information relevant to the safety of the drug				
I agree not to begin clinical investigations until 30 days after FDA's receipt of the IND unless I receive earlier notification by FDA that the studies may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold or financial hold. I agree that an Institutional Review Board (IRB) that complies with the requirements set forth in 21 CFR Part 56 will be responsible for initial and continuing review and approval of each of the studies in the proposed clinical investigation. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.				
19. Sponsor or Sponsor's Authorized Representative				
Prefix	First Name	Middle	Last Name	Title
20. Telephone Number (<i>Include country code if applicable and area code</i>)			21. Facsimile (FAX) Number (<i>Include country code if applicable and area code</i>)	
22. Address				23. Email Address
Address 1 (<i>Street address, P.O. box, company name c/o</i>)				
Address 2 (<i>Apartment, suite, unit, building, floor, etc.</i>)				
City		State/Province/Region		
Country			ZIP or Postal Code	24. Date of Sponsor's Signature (<i>mm/dd/yyyy</i>)

25. Name of Countersigner			
26. Address of Countersigner			27. Email Address
Address 1 (<i>Street address, P.O. box, company name c/o</i>)			
Address 2 (<i>Apartment, suite, unit, building, floor, etc.</i>)			
City	State/Province/Region		
Country	ZIP or Postal Code		WARNING : A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001).
United States of America			
28. Signature of Sponsor or Sponsor's Authorized Representative		29. Signature of Countersigner	
The information below applies only to requirements of the Paperwork Reduction Act of 1995. The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right: <i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."</i> Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff PRASaff@fda.hhs.gov Please do NOT send your completed form to this PRA Staff email address.			