FORM FDA 1571

# INVESTIGATIONAL NEW DRUG APPLICATION (IND)

NOTE: No drug may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40).

## 1. NAME OF SPONSOR

{{sponsor\_name}}

## 2. DATE OF SUBMISSION

{{submission\_date}}

## 3. ADDRESS (Number, Street, City, State, ZIP Code)

{{sponsor\_address}}

## 4. TELEPHONE NUMBER

{{sponsor\_phone}}

## 5. NAME(S) OF DRUG (Include all available names: Trade, Generic, Chemical, Code)

{{drug\_name}}

## 6. IND NUMBER (If previously assigned)

{{ind\_number}}

## 7. INDICATION(S) (Covered by this submission)

{{indication}}

## 8. PHASE(S) OF CLINICAL INVESTIGATION TO BE CONDUCTED

☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Other (Specify): {{other\_phase}}

## 9. LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (INDs), NEW DRUG APPLICATIONS (NDAs), DRUG MASTER FILES (DMFs), AND INVESTIGATIONAL DEVICE EXEMPTIONS (IDEs) REFERENCED IN THIS APPLICATION

{{referenced\_applications}}

## 10. IND SUBMISSION SHOULD BE CONSECUTIVELY NUMBERED. THE INITIAL IND SHOULD BE NUMBERED SERIAL NO. 0000. THE NEXT SUBMISSION (e.g., Amendment, Report, or Correspondence) SHOULD BE NUMBERED SERIAL NO. 0001. SUBSEQUENT SUBMISSIONS SHOULD BE NUMBERED CONSECUTIVELY IN THE ORDER IN WHICH THEY ARE SUBMITTED.

SERIAL NO.: {{serial\_number}}

## 11. THIS SUBMISSION CONTAINS THE FOLLOWING (Check all that apply)

☐ INITIAL INVESTIGATIONAL NEW DRUG APPLICATION (IND)

☐ PROTOCOL AMENDMENT(S): {{protocol\_amendment\_details}}

☐ NEW PROTOCOL: {{new\_protocol\_details}}

☐ CHANGE IN PROTOCOL: {{protocol\_change\_details}}

☐ NEW INVESTIGATOR: {{new\_investigator\_details}}

☐ RESPONSE TO CLINICAL HOLD: {{clinical\_hold\_response\_details}}

☐ REQUEST FOR REINSTATEMENT OF IND THAT IS WITHDRAWN, INACTIVATED, TERMINATED OR DISCONTINUED: {{reinstatement\_details}}

☐ INFORMATION AMENDMENT(S): {{info\_amendment\_details}}

☐ CHEMISTRY/MICROBIOLOGY: {{chemistry\_details}}

☐ PHARMACOLOGY/TOXICOLOGY: {{pharmacology\_details}}

☐ CLINICAL: {{clinical\_details}}

☐ ANNUAL REPORT: {{annual\_report\_details}}

☐ GENERAL CORRESPONDENCE: {{correspondence\_details}}

☐ RESPONSE TO FDA REQUEST FOR INFORMATION: {{fda\_response\_details}}

☐ OTHER (Specify): {{other\_submission\_details}}

## 12. NAME AND TITLE OF THE PERSON RESPONSIBLE FOR MONITORING THE CONDUCT AND PROGRESS OF THE CLINICAL INVESTIGATIONS

NAME: {{monitor\_name}}

TITLE: {{monitor\_title}}

## 13. NAME(S) AND TITLE(S) OF THE PERSON(S) RESPONSIBLE FOR REVIEW AND EVALUATION OF INFORMATION RELEVANT TO THE SAFETY OF THE DRUG

NAME: {{safety\_evaluator\_name}}

TITLE: {{safety\_evaluator\_title}}

## 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. 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.

SIGNATURE OF SPONSOR OR SPONSOR'S AUTHORIZED REPRESENTATIVE

DATE: {{signature\_date}}

NAME: {{signature\_name}}

TITLE: {{signature\_title}}

ADDRESS: {{signature\_address}}