### FDA form 1571 – top of page 1

1. **NAME OF SPONSOR**
2. **DATE OF SUBMISSION**
3. **ADDRESS (Number, Street, City, State and Zip Code)**
4. **TELEPHONE NUMBER**
5. **NAME(S) OF DRUG (Include all available names: Trade, Generic, Chemical, Code)**
6. **IND NUMBER (If previously assigned)**
7. **INDICATION(S) (Covered by this submission)**
8. **PHASE(S) OF CLINICAL INVESTIGATION TO BE CONDUCTED:**
   - [ ] PHASE 1
   - [ ] PHASE 2
   - [ ] PHASE 3
   - [ ] OTHER (Specify)
10. **IND submission should be consecutively numbered. The initial IND should be numbered “Serial number: 0000.” The 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.**

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1. Sending overnight is not required. You may send with any carrier – even by regular snail mail. However, knowing the date of FDA receipt is important (it starts the 30 day review clock)! Most people send overnight and avoid sending on a Friday. In any case – you will need confirmation of delivery!!

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**Note:** This should be as broad as possible. This is not the title of a protocol.
For initial submission, check only the IND box. For subsequent submissions, check all that apply.

It’s unlikely that you will ever need to use this area. Leave blank.¹

‘Treatment INDs’ and ‘Treatment Protocols’ are special cases and are not intended for single patient use. Before checking either of these boxes, the sponsor should be thoroughly familiar with the cited regulations and contact the appropriate FDA reviewing division to discuss the proposed treatment use. ‘Charge Request/Notification’ is when you are planning to charge subjects for the study drug. This is rare and must be for a good reason.

¹ 'Treatment INDs' and 'Treatment Protocols' are special cases and are not intended for single patient use. Before checking either of these boxes, the sponsor should be thoroughly familiar with the cited regulations and contact the appropriate FDA reviewing division to discuss the proposed treatment use. 'Charge Request/Notification' is when you are planning to charge subjects for the study drug. This is rare and must be for a good reason.
For initial submission, all boxes will be checked. However, in the actual IND document, many sections may be listed as not applicable or referenced to letters of authorization or even a drug label.

Not applicable to a Sponsor-Investigator. However, you can check ‘No’ to the first part if you like.

For a Sponsor-Investigator IND, this will be the Sponsor (Person in Box 1).

### CONTENTS OF APPLICATION
This application contains the following items: (Check all that apply)

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13. **IS ANY PART OF THE CLINICAL STUDY TO BE CONDUCTED BY A CONTRACT RESEARCH ORGANIZATION?**  
   **YES**  **NO**  
   **IF YES, WILL ANY SPONSOR OBLIGATIONS BE TRANSFERRED TO THE CONTRACT RESEARCH ORGANIZATION?**  
   **YES**  **NO**  
   **IF YES, ATTACH A STATEMENT CONTAINING THE NAME AND ADDRESS OF THE CONTRACT RESEARCH ORGANIZATION, IDENTIFICATION OF THE CLINICAL STUDY, AND A LISTING OF THE OBLIGATIONS TRANSFERRED.**

For a Sponsor-Investigator IND, this will be the Sponsor (Person in Box 1).

Box’s 18 & 19 can be left blank if they duplicate Box’s 3 & 4.

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.

Signed and dated by the Sponsor. Date in box 20 is the day the sponsor signs the form! Does not have to match the submission date.

Original usually ‘front to back’. Original goes to FDA but make a good copy for yourself!

Required by regulation to submit with each submission to the IND.