Form FDA 1571: Guidance Document for Form Completion

Purpose of the Form FDA 1571:
• This is a form that accompanies the cover letter and submission.
• Provides the content of the submission.
• Captures information tracked by FDA systems.

General Guidance:
• Field numbers below correspond to the numbered boxes on the Form FDA 1571.
• All information presented in this guidance is a supplement to the guidance provided by the FDA:
  o (http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm)
    ▪ This is the link to all the FDA forms, scroll down to the "1571" noted in the forms column to ensure use of the most current instructions.
• Version of the Form FDA 1571:
  o Recommend always going to below link to ensure use of most current Form FDA 1571:
    ▪ http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm
      • This is the link to all the FDA forms, scroll down to the "1571" noted in the forms column to ensure use of the most current form.
      ▪ The expiration date for the current form can be found on the top right corner and the version date in the bottom left footer. If an update is made, a new date would be indicated in the left footer.
  o In the instance when the FDA’s Office of Management and Budget (OMB) has not posted an updated Form FDA 1571 and the expired version is the only one available on the website, it is acceptable to use the expired form. Always confirm the most current form is being used by accessing the form on the FDA web site using the link provided above.
  o There is no need to prepare and sign a new Form FDA 1571 when the OMB expiration date has been reached
  o Sponsors should complete the form, but not modify the security settings or make other changes to the form since the approved, secured, posted form has been tested, approved and allows for automated processing of submissions to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).
• Information entered in all sections of the Form FDA 1571 should be correct and complete for extraction purposes.
• Instructions for the Completion:
  o All sections must be completed, as applicable.
  o Corrections to typographical errors using correction fluid (e.g. "white out") and correction tape are not allowed. Hand corrections to the Form FDA 1571 may be made by crossing out incorrect information with a single line, signing and dating the error by the Sponsor-Investigator.
• Instructions for Document Checks:
  o Confirm the Form FDA 1571 is typed or handwritten in ink (indelible, black or blue ink). Note boxes 25 and 26, may be completed electronically when using an electronic system and all applicable rules are to be followed for electronic signature per the system being used.
• General issues to avoid
  o Incorrect or missing information.
• Incorrect or missing application number.
• Information that’s inconsistent with the information in the Electronic Common Technical Document (eCTD) us-regional.xml or cover letter.
• Using dates, which span over a long period of time, on the form itself, in the cover letter and/or the eCTD us-regional.xml.
• Using forms which are not current. The most current form noted on the FDA website should be used (even if it has expired).

• Where to send the Application (when submitting paper version):
  o The initial IND submission and each subsequent submission to the IND should be accompanied by a Form FDA 1571 and the form must be submitted in triplicate (the original and two photocopies are acceptable). Mailing addresses for initial IND submissions are:
    ▪ **For a Drug:**
      • Food and Drug Administration
        Center for Drug Evaluation and Research
        Central Document Room
        5901-B Ammendale Rd.
        Beltsville, Md. 20705-1266
    ▪ **For a Therapeutic Biological Product:**
      • Food and Drug Administration
        Center for Drug Evaluation and Research
        Therapeutic Biological Products Document Room
        5901-B Ammendale Road
        Beltsville, MD 20705-1266
  o For electronic submissions, provide a blank fillable form (so that the meta data can be extracted) in addition to submitting a scanned completed PDF form.
Field 1:
- The name in Field 1 does not have to exactly match to CV or medical/professional license but should be clear it is the same person when an individual, versus company or agency, is listed as a sponsor.

Field 3/4:
- If the sponsor is the pharmaceutical company, clarification should be obtained from the sponsor company on which address should be utilized as many companies have multiple addresses.
- The zip code field is a free text field to allow foreign companies to type in code that would be relevant to their area. It does not have a 5 digit limit. The only place there is a 5 digit limit is Field 24, the address of the Countersigned. All other zip codes are free text, so letters and numbers may be entered. If the ZIP/postal code are left blank, the page cannot be finalized and “NA” should be listed in this field (e.g. Ireland).

Field 5:
- Provide the unique ingredient identifier (UNII) term and code for active substances.
- The UNII number can be found at: [http://fdasis.nlm.nih.gov/srs/srs.jsp](http://fdasis.nlm.nih.gov/srs/srs.jsp)
Field 7:
- The proposed indication is the disease or condition that the clinical trial/drug is treating, preventing, mitigating, curing, or diagnosing.

Field 8:
- The phase to be entered is the current phase the drug is in, as opposed to the future phase to be conducted in. 'Other' should be used if the trial is anything other than Phase 1, 2 or 3, i.e. IV, or 1a etc, NA should not be entered.

Field 10:
- The Form FDA 1571 is not required for pre-submissions to an IND. If the Form FDA 1571 is included with a pre-submission to allow for automated processing and/or to indicate the purpose for the submission, the serial number field should be left blank.
Field 14:

- Transfer of Obligation is when the sponsor turns over responsibility of specific activities of the clinical trial to a CRO. Transfer of Responsibility is when the sponsor legally and contractually hands work over to another party.

- Is any part of the clinical study to be conducted by a contract research organization?
  - If yes, will any sponsor obligations be transferred to the contract research organization?
  - If yes, provide a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred (use continuation page).

- Per 21CRF312.52 Transfer of obligations to a contract research organization. (a) A sponsor may transfer responsibility for any or all of the obligations set forth in this part to a contract research organization. Any such transfer shall be described in writing. If not all obligations are transferred, the writing is required to describe each of the obligations being assumed by the contract research organization. If all obligations are transferred, a general statement that all obligations have been transferred is acceptable. Any obligation not covered by the written description shall be deemed not to have been transferred. (b) A contract research organization that assumes any obligation of a sponsor shall comply with the specific regulations in this chapter and shall be subject to the same regulatory action as a sponsor for failure to comply with any obligation assumed under these regulations. Thus, all references to “sponsor” in this part apply to a contract research organization to the extent that it assumes one or more obligations of the sponsor.

- If there has been no change in the contract research organization information provided in the initial submission (or subsequent amendment), the sponsor is not required to resubmit it with each amendment to the IND, but may incorporate the information by reference (21 CFR 312.23(b)). This means you should check “yes” where appropriate and on the continuation page you should reference the submission date and sequence that contains the information.
Field 17:
- The person in Field 17 should be the same person who signs Field 25. When signing electronically, a proxy may sign on behalf of the person in Field 17 and should be noted in the text of the e-signature.
- When utilizing e-signature you must follow the training as provided by your sponsor for e-signatures in line with Part 11 compliance.
- This person takes responsibility for the application and agrees to comply with all applicable laws and regulations. A third party provider contracted solely to compile, publish, and dispatch an application via the FDA ESG cannot sign-off on behalf of the Sponsor prior to submission to the FDA. As a result, a 3rd party provider cannot be the proxy.

Field 23:
- The submission must be countersigned if the person signing the application does not reside or have a place of business in the US. If the Sponsor’s Authorized Representative is located in the US, no additional information is needed.

Field 24:
- There is a 5-9 digit limit in the countersigned area for the postal/zip code section.