# *Form FDA 1572:*
# *Guidance Document for Form Completion*

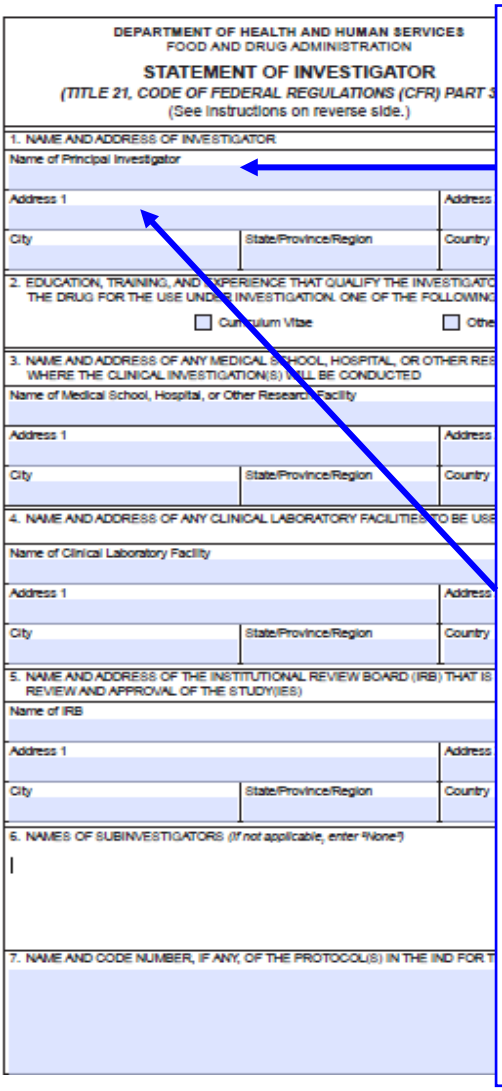
***Purpose of the Form FDA 1572:***

- The Statement of Investigator, Form FDA 1572, is an agreement signed by the principal investigator (PI) to provide certain information to the sponsor and assuring that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.
- Form FDA 1572 is required for each PI participating in a clinical trial that is to be conducted under a US IND.

***General Guidance:***

- The purpose of this document is to provide guidance on completion of the Form FDA 1572 form. This form does not address use for principal investigators outside the US. Use in non-US sites should be evaluated and determined by each sponsor.
- All information presented in this guidance is a supplement to the FDA guidance titled "Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572)".
- Version of the Form FDA 1572:
    - Recommend always going to below link to ensure use of most current Form FDA 1572:
        - http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm
            - This is the link to all the FDA forms, scroll down to the "1572" noted in the forms column to ensure use of the most current form and instructions.
        - 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.
- Per the FDA guidance, there are two instances when it is necessary for the principal investigator to complete and sign a new Form FDA 1572 which include the following:
    - When a principal investigator is participating in a new protocol that has been added to the IND.
    - When a new principal investigator is added to the study (21 CFR 312.53(c)).
- If there are changes to information contained on the Form FDA 1572 that has already been submitted to the sponsor, all revisions must be made and submitted to the sponsor. It is then the accountability/reponsibility of the sponsor to submit to the FDA per their processes.
- In the instance when the FDA's Office of Management and Budget (OMB) has not posted an updated Form FDA 1572 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.
- There is no need to prepare and sign a new Form FDA 1572 when the OMB expiration date has been reached.
- All entries must be legible and complete (typed or handwritten) and completed in English.
- Do not leave any section of the form blank. Use "N/A" or "None" as applicable. Exception is in section 7, for phase 4 studies.
- Corrections to typographical errors using correction fluid (e.g. "White Out") and correction tape are not allowed.
- Hand corrections to the Form FDA 1572 may be made by the Principal Investigator by crossing out incorrect information with a single line, signing and dating the error.

- If using paper, rather than an electronic form, and if the Form FDA 1572 is not a one page, double-sided document, all pages are to be attached together so that there is assurance that the complete form was read, understood and completed by the principal investigator who is to sign the form.
- If additional space is needed for a specific section, continuation pages should be used. Ensure additional pages are linked to the Form FDA 1572 by some tracking mechanism. Reference the addendum in the corresponding section of the form.
- If submitting the form electronically, to the sponsor, the site is to follow any electronic submission and signature guidance as provided by the sponsor company.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

*(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 3*

(See instructions on reverse side.)

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator

Address 1 | Address

City | State/Province/Region | Country

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATO
THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING

☐ Curriculum Vitae ☐ Othe

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RES
WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED

Name of Medical School, Hospital, or Other Research Facility

Address 1 | Address

City | State/Province/Region | Country

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USE

Name of Clinical Laboratory Facility

Address 1 | Address

City | State/Province/Region | Country

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS
REVIEW AND APPROVAL OF THE STUDY(IES)

Name of IRB

Address 1 | Address

City | State/Province/Region | Country

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR T

**SECTION 1**

This section is to document the address where the investigator can be reached by mail or in person.

**Name:**

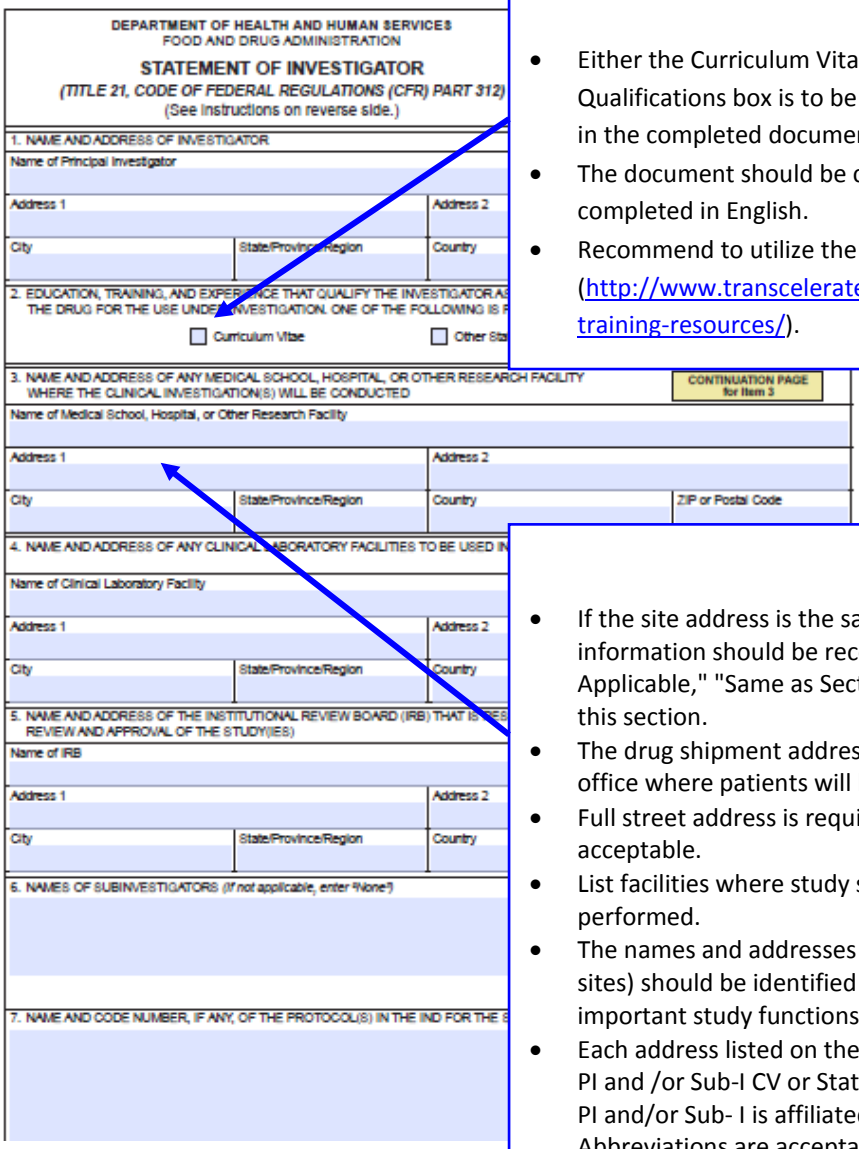
- Should contain investigator's full legal name.
  - Name should match the medical/professional license (if applicable) & Curriculum Vitae (CV). The name does not have to exactly match, but should be clear it is the same person.
  - If name on license/CV is different than name on Form FDA 1572, then ask PI to provide supporting documentation (such as naturalization papers or other documentation) to confirm name recorded.
- Degree:
  - Listing is preferred, but not required.

**Address:**

- The full mailing address of the PI is required; however, it does not have to be the same as the address listed in section 3.
- Listing a PO Box by itself is not acceptable.
- Investigator's telephone numbers are not required.
- Investigator's address may be different from the drug shipment address.
- Country is to be included, if outside the US.
- Address should match the information on the investigator's CV.

**Co-Investigator:**

- "Co-Investigator" is not defined in FDA regulations, therefore if there are 2 investigators at a site requesting to be PIs; one must be designated as a Sub-investigator.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

**STATEMENT OF INVESTIGATOR**

*(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)*

(See instructions on reverse side.)

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator

Address 1 | Address 2

City | State/Province/Region | Country

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS ... THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS ...

☐ Curriculum Vitae ☐ Other Sta...

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — CONTINUATION PAGE for Item 3

Name of Medical School, Hospital, or Other Research Facility

Address 1 | Address 2

City | State/Province/Region | Country | ZIP or Postal Code

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN ...

Name of Clinical Laboratory Facility

Address 1 | Address 2

City | State/Province/Region | Country

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS ... REVIEW AND APPROVAL OF THE STUDY(IES)

Name of IRB

Address 1 | Address 2

City | State/Province/Region | Country

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

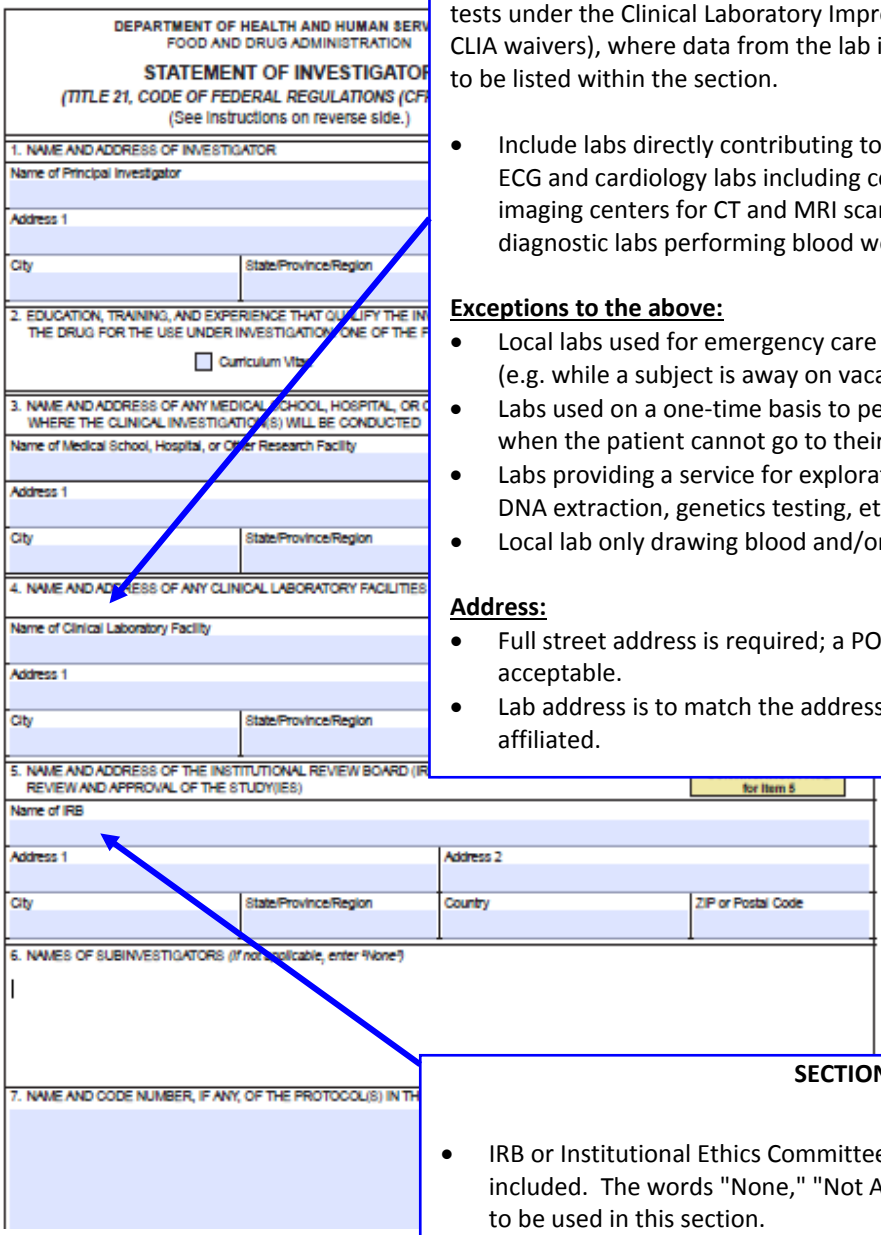
7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE S...

**SECTION 2**

- Either the Curriculum Vitae (CV) box or the Other Statement of Qualifications box is to be checked to indicate that investigator has sent in the completed documentation of experience.
- The document should be current at the time of study start and completed in English.
- Recommend to utilize the TransCelerate CV template which is located at (http://www.transceleratebiopharmainc.com/site-qualification-and-training-resources/).

**SECTION 3**

- If the site address is the same as the section 1 address then the same information should be recorded in section 3 and the words "None," "Not Applicable," "Same as Section 1" and "See Above" are not to be used in this section.
- The drug shipment address should be clearly labeled if different than office where patients will be seen.
- Full street address is required; a PO Box number by itself is not acceptable.
- List facilities where study subjects will be seen and study procedures performed.
- The names and addresses of each of the study sites (satellite/ancillary sites) should be identified in this section along with facilities where important study functions are performed.
- Each address listed on the Form FDA 1572 should also be reflected on the PI and /or Sub-I CV or Statement of Qualifications demonstrating that the PI and/or Sub- I is affiliated with the center were patients will be seen. Abbreviations are acceptable for names of facilities.




**SECTION 4**

This section is to document laboratories (labs) being utilized for the study. Any lab which is used, central or local labs (including those performing lab tests under the Clinical Laboratory Improvement Amendments of 1988 or CLIA waivers), where data from the lab is being used for the clinical trial, is to be listed within the section.

- Include labs directly contributing to or supporting the clinical trial (e.g. ECG and cardiology labs including central or local reading ECG centers, imaging centers for CT and MRI scans, Ophthalmology facilities and diagnostic labs performing blood work) should be listed.

**Exceptions to the above:**

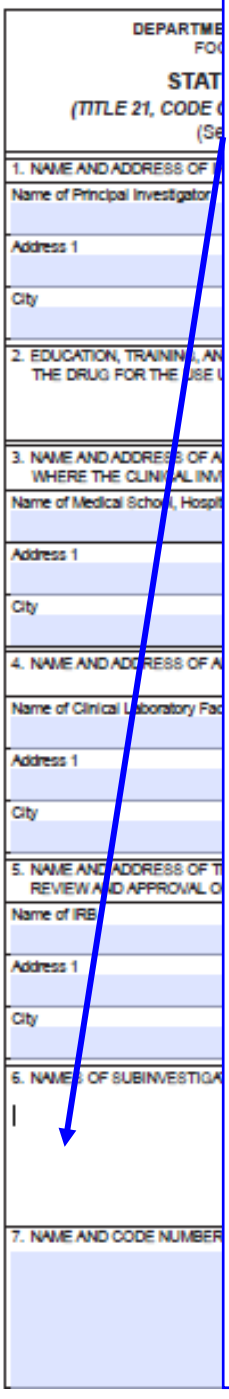
- Local labs used for emergency care and/or SAEs or in exceptional cases (e.g. while a subject is away on vacation, etc.).
- Labs used on a one-time basis to perform lab tests (e.g. a lab used when the patient cannot go to their regular lab).
- Labs providing a service for exploratory objectives of the study (e.g. DNA extraction, genetics testing, etc.).
- Local lab only drawing blood and/or processing the specimen.

**Address:**

- Full street address is required; a PO Box number by itself is not acceptable.
- Lab address is to match the address on the lab certification or be affiliated.

**SECTION 5**

- IRB or Institutional Ethics Committee (IEC) name and address must be included. The words "None," "Not Applicable, and "See Above" are not to be used in this section.
- Full street address is required; a PO Box number by itself is not acceptable.
- Name and address of IRB/IEC should match other documentation (IRB/IEC approval letter, roster or letterhead).
- The local IRB/IEC should only be listed if assuming full ethics committee responsibility.




**SECTION 6**

The decision regarding which site personnel are listed as sub-investigators is the responsibility of the PI. The following guidance can be utilized to determine which staff members are to be included in this section:

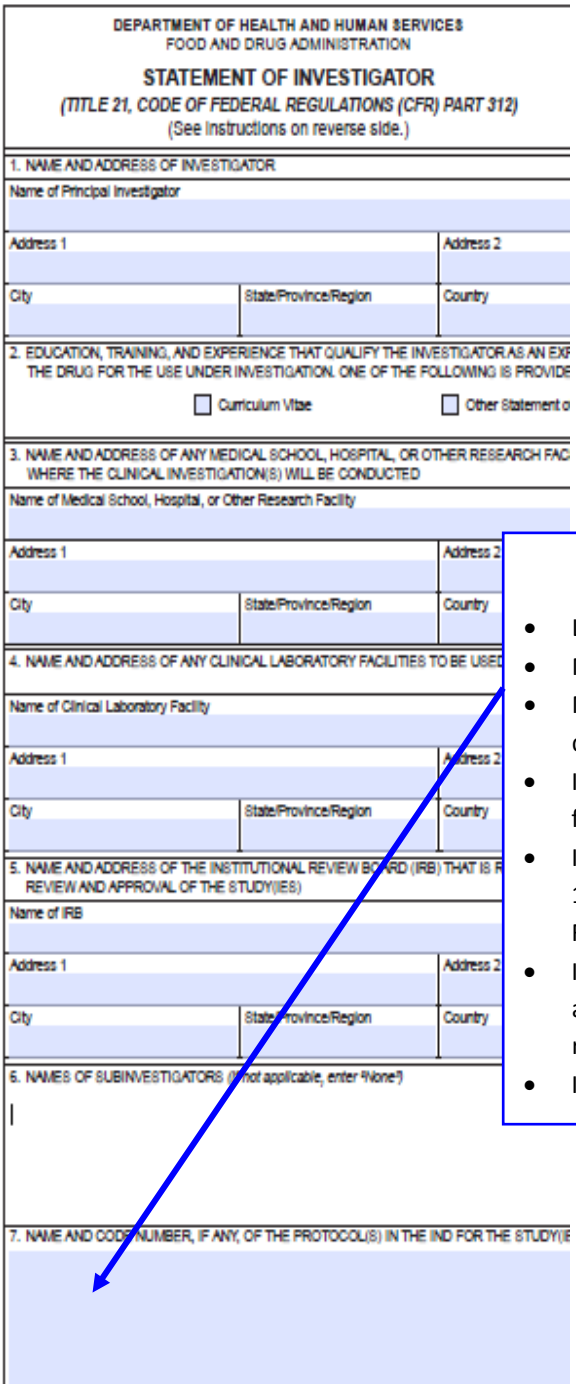
- WHO IS a SUB-INVESTIGATOR:
  - Any individual assisting the principal investigator in the conduct of the investigation and make a direct and significant contribution to the data.
  - Anyone who makes clinical decisions.
  - Anyone who forms medical opinions about eligibility, diagnosis, treatment or the clinical status of the patients in a study.
  - Anyone who is performing significant study activities related to evaluation of study subjects and makes a direct and significant contribution to the data.
  - Physicians who perform the clinical assessment of adverse events and serious adverse events.
  - Anyone who performs critical trial-related procedures.
  - Other professionals who assist the principal investigator in the design and conduct of the investigation.
  - Anyone who makes calculations in the preparation of study medication.

- WHO IS NOT a SUB-INVESTIGATOR:
  - Personnel that perform administrative tasks.
  - A person who does not make medical decisions.
  - Technicians and other assistants who assume no responsibility for the conduct of the study.

- Rotational staff can be listed on the delegation log.
- Generally, a research coordinator has a greater role in performing critical study functions and making direct and significant contributions to the data. For example, a research coordinator often recruits subjects, collects and evaluates study data, and maintains study records. Therefore, the research coordinator should usually be listed.
- Staff credentials should not be listed if the staff member is not licensed in the state where they are doing the research and/or they are not working in the capacity per their licensure (with the exception of VA Licensed personnel).
- Staff titles are not necessary (i.e. Study Coordinator, Rater, etc.).
- There should be at least one sub-investigator listed to ensure medical care is provided to the subject when the Principal Investigator is not available.
- If the PI is not a MD or DO (or dentist, if applicable), at least one Sub-Investigator must meet this qualification.

**Name:**

- Should contain the sub- investigator's full legal name.
  - Name should match the medical/professional license (if applicable) & CV. The name does not have to exactly match, but should be clear it is the same person.
  - If name on license/CV is different than name on Form FDA 1572, then ask investigator to provide supporting documentation (such as naturalization papers or other documentation) to confirm name recorded.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

**STATEMENT OF INVESTIGATOR**

*(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)*

(See instructions on reverse side.)

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator

Address 1 | Address 2

City | State/Province/Region | Country

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXP
THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDE

☐ Curriculum Vitae ☐ Other Statement o

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FAC
WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED

Name of Medical School, Hospital, or Other Research Facility

Address 1 | Address 2

City | State/Province/Region | Country

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED

Name of Clinical Laboratory Facility

Address 1 | Address 2

City | State/Province/Region | Country

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS R
REVIEW AND APPROVAL OF THE STUDY(IES)

Name of IRB

Address 1 | Address 2

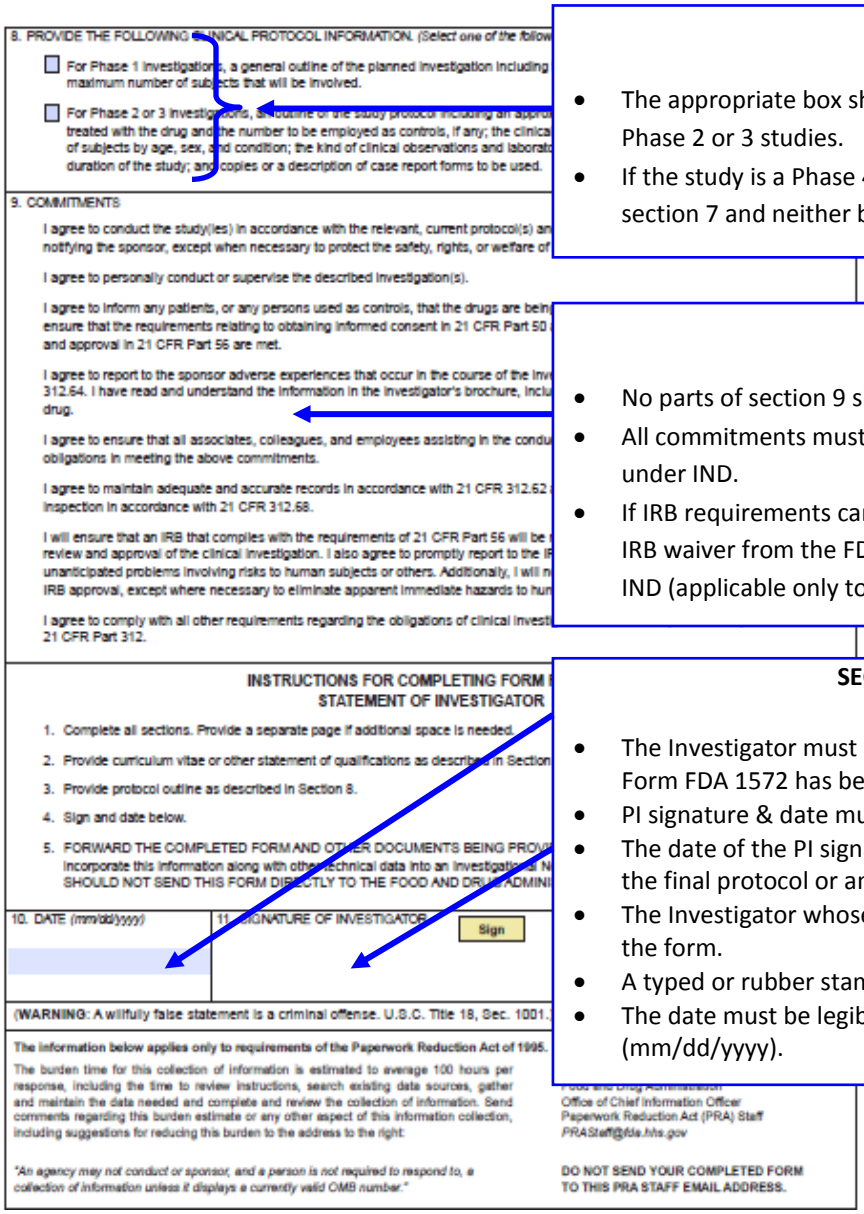
City | State/Province/Region | Country

6. NAMES OF SUBINVESTIGATORS (If not applicable, enter "None")

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IE

**SECTION 7**

- List the study number and full title of the protocol in English.
- May include sponsor.
- May include a supplemental institutional identification code, if directed by the sponsor.
- If a protocol amendment resulted in a title change, all revised forms submitted thereafter must include the updated title.
- If there is a typographical error in the study title the Form FDA 1572 is still acceptable, but should be corrected if a revised Form FDA 1572 is generated.
- If there is a typographical error in the protocol #, compound #, and/or IND #, the Form FDA 1572 is not acceptable and must be revised.
- If study is Phase IV, it must be documented in this section.


8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select one of the follow

☐ For Phase 1 investigations, a general outline of the planned investigation including maximum number of subjects that will be involved.

☐ For Phase 2 or 3 investigations, an outline of the study protocol including an approp treated with the drug and the number to be employed as controls, if any; the clinica of subjects by age, sex, and condition; the kind of clinical observations and laborato duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) an notifying the sponsor, except when necessary to protect the safety, rights, or welfare of

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are bein ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the inv 312.64. I have read and understand the information in the investigator's brochure, inclu drug.

I agree to ensure that all associates, colleagues, and employees assisting in the condu obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be review and approval of the clinical investigation. I also agree to promptly report to the IR unanticipated problems involving risks to human subjects or others. Additionally, I will n IRB approval, except where necessary to eliminate apparent immediate hazards to hun

I agree to comply with all other requirements regarding the obligations of clinical investi 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM
STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as describ in Section
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROV incorporate this information along with other technical data into an investigational N SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINI

10. DATE (mm/dd/yyyy) | 11. SIGNATURE OF INVESTIGATOR | Sign

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.

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:

"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."

Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

**SECTION 8**

- The appropriate box should be checked: Phase 1 studies or Phase 2 or 3 studies.
- If the study is a Phase 4 study, this should be recorded in section 7 and neither box will be checked.

**SECTION 9**

- No parts of section 9 should be crossed out.
- All commitments must be accepted if conducting the trial under IND.
- If IRB requirements cannot be met for non-US sites then an IRB waiver from the FDA must be available for the study or IND (applicable only to non-US sites).

**SECTIONS 10 & 11**

- The Investigator must date his/her own signature after the Form FDA 1572 has been completed.
- PI signature & date must be recognizable and accurate.
- The date of the PI signature should not pre-date the date of the final protocol or amendment to the protocol, if applicable.
- The Investigator whose name appears in section 1 must sign the form.
- A typed or rubber stamp signature is not acceptable.
- The date must be legible and follows the form format, (mm/dd/yyyy).