

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

(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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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

FIRST CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

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Name of Clinical Laboratory Facility

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CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

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Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

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1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

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Name of IRB

Address 1

Address 2

City

State/Province/Region

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

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I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
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(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

THIRD CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIFTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

(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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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

FIRST CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

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FOURTH CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

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City	State/Province/Region	Country	ZIP or Postal Code

FIRST CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

SECOND CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
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Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

THIRD CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIFTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

(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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

**DO NOT SEND YOUR COMPLETED FORM
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FIRST CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

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Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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THIRD CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

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FOURTH CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

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City	State/Province/Region	Country	ZIP or Postal Code

FIRST CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

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Name of Clinical Laboratory Facility

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SECOND CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

THIRD CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

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City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIFTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY
(Enter additional names and addresses below.)**

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
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Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

(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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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

FIRST CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

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FOURTH CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

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FIRST CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

SECOND CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

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THIRD CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

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FOURTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIFTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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

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I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
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Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

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CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

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

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Address 1

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

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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

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Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

(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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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

FIRST CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

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Name of Medical School, Hospital, or Other Research Facility

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City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

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Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIRST CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

SECOND CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

THIRD CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIFTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY
(Enter additional names and addresses below.)**

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

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

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Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

**DO NOT SEND YOUR COMPLETED FORM
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FIRST CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

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FOURTH CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIRST CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

SECOND CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

THIRD CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIFTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY
(Enter additional names and addresses below.)**

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

(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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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

FIRST CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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Name of Medical School, Hospital, or Other Research Facility

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City	State/Province/Region	Country	ZIP or Postal Code

SECOND CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

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Name of Medical School, Hospital, or Other Research Facility

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Name of Medical School, Hospital, or Other Research Facility

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City	State/Province/Region	Country	ZIP or Postal Code

THIRD CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
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Name of Medical School, Hospital, or Other Research Facility

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City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIRST CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

SECOND CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

THIRD CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIFTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

(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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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FIRST CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

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CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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Address 1		Address 2	
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CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

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

Name of IRB

Address 1

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

(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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
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Name of IRB

Address 1		Address 2	
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CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

(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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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

FIRST CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

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City	State/Province/Region	Country	ZIP or Postal Code

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FIRST CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

SECOND CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

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City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

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Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

FIFTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY
(Enter additional names and addresses below.)**

Name of Clinical Laboratory Facility

Address 1		Address 2	
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City	State/Province/Region	Country	ZIP or Postal Code
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Name of Clinical Laboratory Facility

Address 1		Address 2	
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City	State/Province/Region	Country	ZIP or Postal Code
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Name of Clinical Laboratory Facility

Address 1		Address 2	
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City	State/Province/Region	Country	ZIP or Postal Code
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Name of Clinical Laboratory Facility

Address 1		Address 2	
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City	State/Province/Region	Country	ZIP or Postal Code
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Name of Clinical Laboratory Facility

Address 1		Address 2	
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Name of Clinical Laboratory Facility

Address 1		Address 2	
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City	State/Province/Region	Country	ZIP or Postal Code
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CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

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City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

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City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

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

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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:

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Name of Medical School, Hospital, or Other Research Facility

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Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

THIRD CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIFTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY
(Enter additional names and addresses below.)**

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

(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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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

FIRST CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

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FOURTH CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

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Name of Medical School, Hospital, or Other Research Facility

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City	State/Province/Region	Country	ZIP or Postal Code

FIRST CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

SECOND CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

THIRD CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIFTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)

**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.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select **one of the following.)**

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY 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

ZIP or Postal Code

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

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

Name of IRB

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

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

See continuation page

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one of the following.)**

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated 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) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

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 being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review 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 investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for 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 responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
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 described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR
Please See Box 11	

(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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

**DO NOT SEND YOUR COMPLETED FORM
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FIRST CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

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Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

THIRD CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 3**NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED (Enter additional names and addresses below.)**

Name of Medical School, Hospital, or Other Research Facility

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Name of Medical School, Hospital, or Other Research Facility

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City	State/Province/Region	Country	ZIP or Postal Code

FIRST CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

SECOND CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

THIRD CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FOURTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***(Enter additional names and addresses below.)*

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

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Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

FIFTH CONTINUATION PAGE FOR ITEM 4**NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY
(Enter additional names and addresses below.)**

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of Clinical Laboratory Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 5**NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW
AND APPROVAL OF THE STUDY(IES) (*Enter additional names and addresses below.*)**

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Name of IRB

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

CONTINUATION PAGE FOR ITEM 6

NAMES OF SUBINVESTIGATORS (Enter additional names below.)