Cover Page

Release Date: June 23, 2025

ClinicalTrials.gov ID: NCT06062810

Unique Protocol ID: ANDA 220176

Brief Title: Pharmacogenomics ANDA SNP Clinical Study - Raloxifene and Single Nucleotide Polymorphisms (Drugs-SNPs)

Official Title: Explore the Relationship Between Single Nucleotide Polymorphisms and Raloxifene Response and Toxicity in Patients With Breast Cancer LCIS.

Secondary IDs: FWA00015357 [Registry ID: HHS, Human Protections Administrator]
NPI - 1831468511 [Registry ID: HHS, Health Care Provider Individual]
NPI - 1023387701 [Registry ID: HHS, Health Care Provider Organization]
IRB00009424 [Registry ID: HHS, IRB]
IORG0007849 [Registry ID: HHS, IORG]
ANDA 220176 [Registry ID: FDA, ANDA]

Contents

21 CFR 312.23(a)(1)(v)
A commitment to conduct the investigation in accordance with all other applicable regulatory requirements.

Statement

I write the **commitment** with respect to each clinical study involving human subjects that it either will be conducted in compliance with the institutional review board regulations in part 56 or will not be subject to the regulations under §56.104 or §56.105; and that it either will be conducted in compliance with the informed consent regulations in part 50 or will not be subject to the regulations under §50.23 and §50.24.

Study Protocol [21 CFR 312.23(a)(6)(iii)] for ANDA SNP Clinical Trial

ANDA SNP - NCT06062810 Clinical Trial

Han Xu, **Sponsor-Investigator** will initiate and conduct the Study Protocol [21 CFR 312.23(a)(6)(iii)].

- **ClinicalTrials.gov ID: NCT06062810**
- **Sponsor:** Han Xu, M.D., Ph.D., FAPCR, **Sponsor-Investigator**, IRB Chair
- **Responsible Party:** Sponsor-Investigator
- **Sponsor-Investigator:** Han Xu, M.D., Ph.D., FAPCR
- **Study Principal Investigator [Principal Investigator (PI)]:** Han Xu, M.D., Ph.D., FAPCR

My protocol will follow the requirements of 21 CFR 312.23(a)(6)(iii).

The protocol is to contain the following, with the specific elements and detail of the protocol reflecting the above distinctions depending on the Phase 2 of the SNP study:

(a) A statement of the objectives and purpose of the study.

Explore the relationship between single nucleotide polymorphisms and raloxifene response and toxicity in patients with breast cancer showing lobular carcinoma in situ (LCIS) (BC-LCIS).

- Correlate ER Gene Single Nucleotide Polymorphisms (SNPs) to Therapeutic Effects of Using raloxifene to Treat Breast Cancer LCIS (BC-LCIS), based on precise sequencing drug target gene via Breast Tissue DNA.
- Correlate UGT Gene Single Nucleotide Polymorphisms (SNPs) to Side Effects of Using raloxifene to Treat Breast Cancer (BC-LCIS), based on precise sequencing drug target gene via Peripheral Blood DNA.

(b) The name and address and a statement of the qualifications (curriculum vitae or **other statement of qualifications**) of sponsor-investigator or each investigator, and the name of each Principal Investigator or sub-investigator (e.g., research fellow, resident) working under the supervision of the sponsor-investigator; the name and address of the research facilities to be used; and the name and address of each reviewing Institutional Review Board.

M**y investigation will follow the requirements of 21 CFR 312.23(a)(6)(iii)(b).**

The name of sponsor-investigator: Han Xu, M.D., Ph.D., Sponsor-Investigator, IRB Chair, Medical Director
The address of sponsor-investigator: 5545 Burnside Drive, Online Site, Rockville, Maryland, 20853

The name of the IRB: IRB00009424 -- Medicine Invention Design Incorporation (MIDI) IRB #1
The Address of the IRB: 5545 Burnside Drive, Online Site, Rockville, Maryland, 20853

The name of the research facility: IORG0007849 -- Medicine Invention Design Incorporation (MIDI)
The address of the research facility: 5545 Burnside Drive, Online Site, Rockville, Maryland, 20853

The statement of the qualifications of Sponsor-Investigator:

- 2020 - Active Member, **Fellow of the APCR (FAPCR)**, Academy of Physicians in Clinical Research (APCR) - APCR Membership Eligibility - Physician Investigator
  - Certificate of Fellow of Academy of Physicians in Clinical Research (FAPCR)
  - Academy of Physicians in Clinical Research (APCR)
    - **PI (Principal Investigator) in clinical trials**
    - **Medical Director of Clinical Research Site**
- 2025-06 - FDA Pre-Assignment IND 173781 for Raloxifene Tablet
  - **Sponsor:** HAN XU
- 2023-08 - **ClinicalTrials.gov ID:** NCT06062810
  - **Sponsor:** Han Xu, M.D., Ph.D., FAPCR, **Sponsor-Investigator**, IRB Chair
  - **Responsible Party:** Sponsor-Investigator
  - **Sponsor-Investigator:** Han Xu, M.D., Ph.D., FAPCR
  - **Study Principal Investigator [Principal Investigator (PI)]:** Han Xu, M.D., Ph.D., FAPCR

(c) The criteria for patient selection and for exclusion of patients and an estimate of the number of patients to be studied.

- Criteria:
- Select 600 Breast Cancer (BC-LCIS) Patients who are suitable for blood-drawing and biopsy.
- Duration at least 90 days
- The usual approach group - Recruit 300 no-placebo double blind random group separated BC-LCIS patients currently used Standard Dose Chemotherapy on Raloxifene Tablet after breast tissue biopsy diagnosis, as the usual approach group.
- The study approach group - Recruit 300 no-placebo double blind random group separated BC-LCIS patients currently used Standard Dose Chemotherapy on Raloxifene Tablet after breast tissue biopsy diagnosis, as the study approach group.
- If any participating patients have serious side effects, they will stop the research.
- If any participating patients have no therapeutic effects, they will stop the research.

- Inclusion Criteria:
- Clinical diagnosis of breast cancer showing lobular carcinoma in situ (LCIS) (BC-LCIS)
- Clinical biopsy diagnosis of breast cancer showing lobular carcinoma in situ (LCIS) (BC-LCIS)
- Suitable for blood-drawing and biopsy
- Random and double blind
- Measurable disease
- Adequate organ functions
- Adequate performance status
- Age 24 years old and over
- Sign an informed consent form.
- Receive blood-drawing and biopsy.

- Exclusion Criteria:
- Mastectomy
- Treatment with other anti-cancer therapies and cannot be stopped currently
- Pregnancy
- Breast-feeding
- The patients with other serious intercurrent illnesses or infectious diseases
- Have more than one different kind of cancer at the same time
- Serious Allergy Tendency
- Thrombus or Bleed Tendency
- Serious Risks or Serious Adverse Events of the drug product
- The prohibition of drug products
- The participating patients have serious side effects.
- The participating patients have no therapeutic effects.

(d) A description of the design of the study, including the kind of control group to be used, if any, and a description of methods to be used to minimize bias on the part of subjects, investigators, and analysts.

The usual approach group, after breast tissue biopsy and peripheral blood-drawing diagnosis, 300 double blind random group separated BC-LCIS patients currently used Standard Dose Chemotherapy on Raloxifene Tablet, based on precise sequencing drug targets' genes, will try to do the following:

- Correlate ER Gene Single Nucleotide Polymorphisms (SNPs) to Therapeutic Effects of Using Raloxifene to Treat Breast Cancer showing lobular carcinoma in situ (LCIS) (BC-LCIS), via Testing Breast Tissue DNA.
- Correlate UGT Gene Single Nucleotide Polymorphisms (SNPs) to Side Effects of Using Raloxifene to Treat Breast Cancer showing lobular carcinoma in situ (BC-LCIS), via Testing Peripheral Blood DNA.

The study approach group, after breast tissue biopsy and peripheral blood-drawing diagnosis, 300 double blind random group separated BC-LCIS patients currently using Standard Dose Chemotherapy Raloxifene Tablet, based on precisely sequencing drug targets' genes, will try to do the following:

- Correlate ER Gene Single Nucleotide Polymorphisms (SNPs) to Therapeutic Effects of Using Raloxifene to Treat Breast Cancer showing lobular carcinoma in situ (LCIS) (BC-LCIS), via Testing Breast tissue DNA.
- Correlate UGT Gene Single Nucleotide Polymorphisms (SNPs) to Side Effects of Using Raloxifene to Treat Breast Cancer showing lobular carcinoma in situ (BC-LCIS), via Testing Peripheral Blood DNA.

The detailed methods:

1) Detect each drug target's whole gene precision sequence of everyone patient for all 600-recruited-double-blind BC-LCIS patients.

➢ Oxford Nanopore Technologies Ltd - Nanopore DNA Sequencing uses electrophoresis to transport an unknown sample through an orifice of 10^{-9} meters in diameter. A nanopore system always contains an electrolytic solutions- when a constant electric field is applied, an electric current can be observed in the system. The magnitude of the electric current density across a nanopore surface depends on the nanopore's dimensions and the composition of DNA or RNA that is occupying the nanopore. Sequencing is made possible because, when close enough to nanopores, samples cause characteristic changes in electric current density across nanopore surfaces. The total charge flowing through a nanopore channel is equal to the integral surface of electric current density flux across the nanopore unit normal surfaces between times t_1 and t_2.

➢ DNA Sequencing

➢ Prepare

✓ Streamlined library prep in as little as 10 minutes.

✓ PCR-free library prep using 400 ng DNA.

✓ PCR option for very low input amounts

✓ Multiplexing options for more cost-effective analysis

➢ Sequence

✓ Real-time sequencing on MinION, GridION or PromethION

➢ Analyses

✓ Real-time analysis with on device or local infrastructure base-calling

✓ Detect DNA modifications using open-source tools.

2) Mutually compare everyone patient drug target whole gene precision sequence for total 600-recruited double-blind BC-LCIS patients.

3) Calculate each drug target gene SNP in all 600-recruited double-blind BC-LCIS patients.

4) Correlate everyone patient drug target gene SNP to everyone patient drug efficacy.

5) Correlate everyone patient drug target gene SNP to everyone patient drug safety.

6) Mutually compare the usual approach group SNPs (300 double blind random group separated BC-LCIS patients) with the study approach group SNPs (300 double blind random group separated BC-LCIS patients).

7) Confirm the relationship between drug target gene SNPs and drug efficacy.

(e) The method for determining the dose(s) to be administered, the planned maximum dosage, and the duration of individual patient exposure to the drug.

The method for determining the dose(s) to be administered:

➢ RALOXIFENE HYDROCHLORIDE tablet, coated (**DAILYMED:** https://dailymed.nlm.nih.gov) (G-1)

➢ RALOXIFENE HYDROCHLORIDE tablet, coated (**DAILYMED:** https://dailymed.nlm.nih.gov) (G-2)

The planned maximum dosage(s):

✧ The usual approach randomization of double-blinding active treatment concurrent control group:

✓ RALOXIFENE HYDROCHLORIDE tablet, coated -- 60 mg orally daily (**NDC** 71209-082-01) (12 weeks)

✧ The study approach randomization of double-blinding active treatment concurrent control group:

✓ RALOXIFENE HYDROCHLORIDE tablet, coated -- 60 mg orally daily (**NDC** 72241-010-22) (12 weeks)

The duration of individual patient exposure to the drug(s):

✧ The usual approach randomization double-blinding active treatment concurrent control group:

✓ RALOXIFENE HYDROCHLORIDE tablet, coated -- 60 mg orally daily (**NDC** 71209-082-01) (12 weeks) (G-1)

✧ The study approach randomization of double-blinding active treatment concurrent control group:

✓ RALOXIFENE HYDROCHLORIDE tablet, coated -- 60 mg orally daily (**NDC** 72241-010-22) (12 weeks) (G-2)

➢ **The duration of individual patient exposure to the drugs:** 90 days

(f) A description of the observations and measurements to be made to fulfill the objectives of the study.

- Sequence precisely each target gene DNA whole chain in breast tissue as follows: Estrogen Receptor (ER).
- Correlate ER Gene Single Nucleotide Polymorphisms (SNPs) to Therapeutic Effects of Using Raloxifene to Treat BC-LCIS, based on precisely sequencing drug target gene via breast tissue DNA.
- Sequence precisely each target gene DNA whole chain in peripheral blood as follows: UDP-glucuronosyltransferase (UGT).
- Correlate UGT Gene Single Nucleotide Polymorphisms (SNPs) to Side Effects of Using Raloxifene to Treat BC-LCIS, based on precisely sequencing drug target gene via Peripheral Blood DNA.
- Oxford Nanopore Technologies Ltd - Nanopore DNA Sequencing uses electrophoresis to transport an unknown sample through an orifice of 10^{-9} meters in diameter. A nanopore system always contains an electrolytic solutions- when a constant electric field is applied, an electric current can be observed in the system. The magnitude of the electric current density across a nanopore surface depends on the nanopore's dimensions and the composition of DNA or RNA that is occupying the nanopore. Sequencing is made possible because, when close enough to nanopores, samples cause characteristic changes in electric current density across nanopore surfaces. The total charge flowing through a nanopore channel is equal to the integral surface of electric current density flux across the nanopore unit normal surfaces between times t_1 and t_2.
- DNA Sequencing
- Prepare
- ✓ Streamlined library prep in as little as 10 minutes.
- ✓ PCR-free library prep using 400 ng DNA.
- ✓ PCR option for very low input amounts
- ✓ Multiplexing options for more cost-effective analysis
- Sequence
- ✓ Real-time sequencing on MinION, GridION or PromethION
- Analyses
- ✓ Real-time analysis with on device or local infrastructure base-calling.
- ✓ Detect DNA modifications using open-source tools.

(g) A description of clinical procedures, laboratory tests, or other measures to be taken to monitor the effects of the drug in human subjects and to minimize risk.

The clinical procedures:

- ✧ Recruit 600 patients of Breast Cancer LCIS (BC-LCIS) who are suitable for blood-drawing and biopsy.
- ✧ The 600 BC-LCIS patients are randomly separated into 2 groups via computer.
- ✧ The usual approach group is 300 BC-LCIS patients.
- ✧ The study approach group is 300 BC-LCIS patients.
- ✧ Every BC-LCIS patient will receive breast tissue biopsy.
- ✧ Keep storing all breast tissue.
- ✧ Every BC-LCIS patient will receive testing for each Target Gene SNP in Breast Tissue DNA as follows: Estrogen Receptor (ER).
- ✧ Every BC-LCIS patient will receive peripheral blood-drawing.
- ✧ Keep storing all peripheral blood.
- ✧ Every BC-LCIS patient will receive testing for each Target Gene SNP in Peripheral Blood DNA as follows: UDP-glucuronosyltransferase (UGT).
- ✧ The usual approach group (300 BC-LCIS patients) for everyone:
- ✓ RALOXIFENE HYDROCHLORIDE tablet, coated -- 60 mg orally daily (**NDC** 71209-082-01) (12 weeks) (G-1)
- ✓ Sequence precisely each target gene DNA whole chain in breast tissue as follows: Estrogen Receptor (ER).
- ✓ Correlate ER Gene Single Nucleotide Polymorphisms (SNPs) to Therapeutic Effects of Using Raloxifene to Treat Breast Cancer showing lobular carcinoma in situ (BC-LCIS), via Testing Breast Tissue DNA.
- ✓ Sequence precisely each target gene DNA whole chain in peripheral blood as follows: UDP-glucuronosyltransferase (UGT).
- ✓ Correlate UGT Gene Single Nucleotide Polymorphisms (SNPs) to Side Effects of Using Raloxifene to Treat Breast Cancer showing lobular carcinoma in situ (BC-LCIS), via Testing Peripheral Blood DNA.

- ✧ The study approach group (300 BC-LCIS patients) for everyone:
- ✓ RALOXIFENE HYDROCHLORIDE tablet, coated -- 60 mg orally daily (**NDC** 72241-010-22) (12 weeks) (G-2)
- ✓ Sequence precisely each target gene DNA whole chain in breast tissue as follows: Estrogen Receptor (ER).
- ✓ Correlate ER Gene Single Nucleotide Polymorphisms (SNPs) to Therapeutic Effects of Using Raloxifene to Treat Breast Cancer showing lobular carcinoma in situ (BC-LCIS), via Testing Breast Tissue DNA.
- ✓ Sequence precisely each target gene DNA whole chain in peripheral blood as follows: UDP-glucuronosyltransferase (UGT).
- ✓ Correlate UGT Gene Single Nucleotide Polymorphisms (SNPs) to Side Effects of Using Raloxifene to Treat Breast Cancer showing lobular carcinoma in situ (BC-LCIS), via Testing Peripheral Blood DNA.
- ✧ Every BC-LCIS patient will receive an image test one time per month.
- ✧ Every BC-LCIS patient will receive blood test one time per week.
- ✧ Every BC-LCIS patient will receive urine test one time per week.
- ✧ Every BC-LCIS patient will receive ECG test one time per week.
- ✧ The clinical study endpoint is BC-LCIS metastasis or growth.
- ✧ The drug efficacy standard is to avoid BC-LCIS metastasis or growth in 90 days.
- ✧ Mutually compare the usual approach group SNPs (300 double-blind random group separated BC-LCIS patients) with the study approach group SNPs (300 double-blind random group separated BC-LCIS patients).
- ✧ Confirm the relationship between drug target gene SNPs and drug efficacy.
- ✧ If the breast tissue biopsy samples of the usual approach group have the same ER Gene SNP as the breast tissue biopsy samples of the study approach group, the relationship between the Raloxifene drug target gene SNP and the Raloxifene drug efficacy can be confirmed, i.e., this ER Gene SNP is the Raloxifene drug target gene SNP relating to the Raloxifene drug efficacy.
- ✧ Confirm the relationship between drug target gene SNPs and drug risk.
- ✧ If the peripheral blood samples of the usual approach group have the same UGT Gene SNP as the peripheral blood samples of the study approach group, the relationship between the Raloxifene drug target gene SNP and the Raloxifene drug risk can be confirmed, i.e., this UGT Gene SNP is the Raloxifene drug target gene SNP relating to the Raloxifene drug risk.

The laboratory tests:

- ✧ Recruit 600 patients of Breast Cancer LCIS who are suitable for blood-drawing and biopsy.
- ✧ Every Breast Cancer LCIS patient will receive peripheral blood-drawing and breast tissue biopsy.
- ✧ Keep storing all peripheral blood and breast tissue.
- ✧ Detect every drug target's whole gene precision sequence of every patient for all 600 BC-LCIS patients.
- ➢ Oxford Nanopore Technologies Ltd - Nanopore DNA Sequencing uses electrophoresis to transport an unknown sample through an orifice of 10^{-9} meters in diameter. A nanopore system always contains an electrolytic solutions- when a constant electric field is applied, an electric current can be observed in the system. The magnitude of the electric current density across a nanopore surface depends on the nanopore's dimensions and the composition of DNA or RNA that is occupying the nanopore. Sequencing is made possible because, when close enough to nanopores, samples cause characteristic changes in electric current density across nanopore surfaces. The total charge flowing through a nanopore channel is equal to the integral surface of electric current density flux across the nanopore unit normal surfaces between times t_1 and t_2.
- ➢ DNA Sequencing
- ➢ Prepare
- ✓ Streamlined library prep in as little as 10 minutes.
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- ✓ PCR option for very low input amounts
- ✓ Multiplexing options for more cost-effective analysis
- ➢ Sequence
- ✓ Real-time sequencing on MinION, GridION or PromethION
- ➢ Analyses
- ✓ Real-time analysis with on device or local infrastructure base-calling.
- ✓ Detect DNA modifications using open-source tools.

- ✧ Every BC-LCIS patient will receive sequencing each target gene DNA whole chain in breast tissue as follows: **Estrogen Receptor (ER)**.
- ✧ Every BC-LCIS patient will receive sequencing each target gene DNA whole chain in peripheral blood as follows: UDP-glucuronosyltransferase (UGT).
- ✧ Mutually compare every drug target whole gene precision sequence of every patient for total 600 BC-LCIS patients.
- ✧ Obtain every-one Drug Target Gene SNP for every Breast Cancer LCIS patient in Breast Tissue DNA as follows: **Estrogen Receptor (ER)**.
- ✧ Obtain every-one Target Gene SNP for every Breast Cancer LCIS patient in Peripheral Blood DNA as follows: UDP-glucuronosyltransferase (UGT).
- ✧ Every BC-LCIS patient will receive an image test one time per month.
- ✧ Every BC-LCIS patient will receive blood test one time per week.
- ✧ Every BC-LCIS patient will receive urine test one time per week.
- ✧ Every BC-LCIS patient will receive ECG test one time per week.

The measures to be taken to monitor the effects of the drug in human subjects:

- ✧ The clinical study endpoint is BC-LCIS metastasis or growth.
- ✧ The drug efficacy standard is to avoid BC-LCIS metastasis or growth in 90 days.
- ✧ Every BC-LCIS patient will receive an image test one time per month.

The measures to be taken to minimize the risks of the drug in human subjects:

- ✧ Every BC-LCIS patient will receive an image test one time per month.
- ✧ Every BC-LCIS patient will receive blood test one time per week.
- ✧ Every BC-LCIS patient will receive urine test one time per week.
- ✧ Every BC-LCIS patient will receive ECG test one time per week.

- ➢ RALOXIFENE HYDROCHLORIDE tablet, coated **DAILYMED** https://dailymed.nlm.nih.gov (Generic-1)
- ➢ RALOXIFENE HYDROCHLORIDE tablet, coated **DAILYMED** https://dailymed.nlm.nih.gov (Generic-2)

21 CFR§56.102 (i)
Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The IRB00009424 must let all subjects sign a written consent form and will let the research NCT06062810 present no more than minimal risk of harm to subjects as well as will let the research NCT06062810 involve no procedures for outside the written consent document context.

21 CFR§56.111 (a) (1)
Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

The study patients of BC-LCIS follow up the standard of care treatment with drug therapy in the RALOXIFENE HYDROCHLORIDE tablet, coated DAILYMED Label (Generic-1) (Generic-2)
If any participating patients have serious side effects, they will stop the research.
If any participating patients have no therapeutic effects, they will stop the research.

My clinical investigation (**NCT06062810**) intends to explore the relationship between **single nucleotide polymorphisms (SNP)** and raloxifene response and toxicity in patients with breast cancer showing lobular carcinoma in situ (LCIS) (BC-LCIS). My investigation information is from exploration studies and is research data from general gene expression analyses in Peripheral Blood Mononuclear Cells and Biopsy Breast Tissue of humans and from **single-nucleotide polymorphism (SNP)** analysis of trial participants.

21 CFR 56.102(g)
Institutional Review Board (IRB) means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects.

21 CFR 56.102(m)
IRB approval means the determination of the IRB that the clinical investigation has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

21 CFR 56.107(e)
No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

I (Han Xu, M.D., Ph.D. i.e., Sponsor i.e., Sponsor-Investigator) as IRB Chair of our IRB (IRB00009424) will only organize the IRB meeting but give up my voting power in the determination of IRB, when I conduct my clinical investigation (NCT06062810).

- 2020 - Active Member, Fellow of the APCR (FAPCR), Academy of Physicians in Clinical Research (APCR) - APCR Membership Eligibility - Physician Investigator
  - Certificate of Fellow of Academy of Physicians in Clinical Research (FAPCR)
  - Academy of Physicians in Clinical Research (APCR)
    - **PI (Principal Investigator) in clinical trials**
    - **Medical Director of Clinical Research Site**
- 2024-08 - FDA Pre-Assignment IND 173781 for Raloxifene Tablet
  - **Sponsor:** HAN XU
- 2025-06 - **ClinicalTrials.gov ID:** NCT06062810
  - **Sponsor:** Han Xu, M.D., Ph.D., FAPCR, **Sponsor-Investigator**, IRB Chair
  - **Responsible Party:** Sponsor-Investigator
  - **Sponsor-Investigator:** Han Xu, M.D., Ph.D., FAPCR
  - **Study Principal Investigator [Principal Investigator (PI)]:** Han Xu, M.D., Ph.D., FAPCR

21 CFR 56.102(k)
Sponsor-investigator means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, … The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator.

21 CFR §50.3 (f)
Sponsor-investigator means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, … The term does not include any person other than an individual, e.g., corporation or agency.

I (**Han Xu, Sponsor-Investigator**) can both initiate and conduct, alone or with others, my clinical investigation. So, I am a qualified investigator for my ANDA SNP oncology drug clinical trial.

21 CFR 312.23(a)(1)(v)
A commitment to conduct the investigation in accordance with all other applicable regulatory requirements.

Statement

I write the **statement** with respect to each clinical study involving human subjects that it either will be conducted in compliance with the institutional review board regulations in part 56 or will not be subject to the regulations under §56.104 or §56.105; and that it either will be conducted in compliance with the informed consent regulations in part 50 or will not be subject to the regulations under §50.23 and §50.24.