The University of Colorado Denver's Department of Obstetrics and Gynecology is conducting a research study looking at how healthy young women have regular periods every month.

How do I know if my daughter can participate?

In order to be eligible your daughter must:
- Be a healthy, normal weight girl, 10-15 years old.
- Have not started her menstrual period.
- Not be taking hormones or birth control pills.
- Not exercise more than 4 hours per week.
- Have no history of kidney or liver disease.
- Have no family history of blood disorders.

If your daughter is interested or you would like more information please contact:

Jennifer Lesh, Study Coordinator
303-724-2046
jennifer.lesh@ucdenver.edu

In order to enroll all participants must meet specific criteria. The criteria listed above is only a partial list of all the requirements to participate in this research study. Only a clinical research staff member can determine eligibility.

Establishment of Regular Ovulation in Normal Menarche, Aim #2
Principal Investigator: Nanette Santoro, MD

University of Colorado Denver School Of Medicine
COMIRB Protocol Number: 11-0551
Adolescent Research Participants Needed

Would your daughter like to participate in a research study and learn more about the changes her body will go through as she grows up?

The University of Colorado Denver's Department of Obstetrics and Gynecology is conducting a research study looking at how healthy young women have regular periods every month.

How do I know if my daughter can participate?

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Establishment of Regular Ovulation in Normal Menarche, Aim #2
Principal Investigator: Nanette Santoro, MD

University of Colorado Denver School Of Medicine
COMIRB Protocol Number: 11-0551
Patient Information Form

Establishment of Regular Ovulation in Normal Menarche, Aim #2
PI: Nanette Santoro, MD
COMIRB Protocol #11-0551

Date: ____________

Child’s Name: ________________________________

Mother’s Name: ______________________________

Father’s Name: ________________________________

Date of Birth: ____________

Ethnicity/Race: (please circle all that apply)

Native American  Asian  Black  White  Hispanic  Other

Phone Numbers

Home: ________________________________

Work: ________________________________

Cell: ________________________________

E-mail: ________________________________

Best method of contact? (please circle)

Home Phone  Work Phone  Cell Phone  E-mail

Home Address:

__________________________________________________________________________

Shipping Address: (if different)

__________________________________________________________________________

Version 2: 29-Apr-2011
Visit #1 Questionnaire for Parent

Establishment of Regular Ovulation in Normal Menarche, Aim #2
PI: Nanette Santoro, MD
COMIRB Protocol #11-0551

APPROVED
JUN 23 2011
COMIRB

Date: ________________

Directions:
Please answer the following questions about your daughter and your family by circling your answer.

Questionnaire answered by:  Mother /  Father /  Legal Guardian (circle one)
Visit #1 Questionnaire for Parent

Establishment of Regular Ovulation in Normal Menarche, Aim #2
PI: Nanette Santoro, MD
COMIRB Protocol #11-0551

Study ID #: ________________

Age Questions

1. How old is your daughter?
   a. 10
   b. 11
   c. 12
   d. 13
   e. 14
   f. 15

2. What grade is she in?
   a. 4th grade
   b. 5th grade
   c. 6th grade
   d. 7th grade
   e. 8th grade
   f. 9th grade
   g. 10th grade
   h. 11th grade
   i. 12th grade

Menstrual and Birth Control History

3. Has your daughter ever had a menstrual period (menstruation)?
   a. No, she has not started having periods (menstruating) yet.
   b. Yes, she has had periods in the past.

4. Has she ever used birth control?
   a. No...........................................................................................(skip to question #6)
   b. Yes

5. Which forms of birth control has she used? Circle all that apply.
   a. Birth control pills (the pill)
   b. Depo-Provera (the shot)
   c. Ortho Evra (the patch)
   d. Nuva Ring (the ring)
   e. Mirena (IUD)
   f. Some other method
   g. Not sure
Visit #1 Questionnaire for Parent

Establishment of Regular Ovulation in Normal Menarche, Aim #2
PI: Nanette Santoro, MD
COMIRB Protocol #11-0551

Study ID #: _____________

Medical History
6. Does your daughter have an eating disorder?
   a. She does not have an eating disorder
   b. She has Anorexia Nervosa
   c. She has Bulimia
   d. I am not sure

7. Has your daughter ever been told by a doctor that she has a kidney or liver disease?
   a. Yes
   b. No
   c. Not sure

8. Does she have diabetes?
   a. Yes
   b. No

9. Does she take Insulin shots every day?
   a. Yes
   b. No
   c. I don’t know

10. Does your daughter have any chronic health conditions? (This means a health condition for which she needs regular medication or doctor visits for treatment)
    a. Yes. Please write the name here: ____________________________
    b. No

Medication Questions
11. Has your daughter ever received steroid medication (such as: Prednisone, Decadron, Hydrocortisone) for an illness over the past three months?
    a. Yes
    b. No
    c. I am not sure

12. Has she ever been on medicine for the treatment of cancer (chemotherapy) over the past three months?
    a. Yes
    b. No
    c. I am not sure
13. Has she taken prescription medication (not including Tylenol, Advil/Motrin or vitamins) over the past three months?
   a. Yes
   b. No...........................................................................................................(skip to question #15)
   c. I am not sure.........................................................................................(skip to question #15)

14. Please write the names of any medicine your daughter has taken over the past three months:

   ________________________________________________________________

   ________________________________________________________________

   ________________________________________________________________

   ________________________________________________________________

15. If your daughter has taken any medicine not prescribed by a doctor that she or someone else got for her over the past three months please write the names here:

   ________________________________________________________________

   ________________________________________________________________

   ________________________________________________________________

   ________________________________________________________________
Visit #1 Questionnaire for Parent

Family Medical History Questions

16. Do you have anyone in your family with a serious weight problem? Someone who is very, very heavy?

Please answer for your daughter. Circle all that apply.

My daughter’s.............

a. None of the people listed below are very, very heavy
b. Mother
c. Father
d. Sister or brother
e. Grandmother on mother’s side
f. Grandfather on mother’s side
g. Grandmother on father’s side
h. Grandfather on father’s side
i. Aunt or uncle on mother’s side
j. Aunt or uncle on father’s side
k. Cousin on mother’s side
l. Cousin on father’s side
m. I don’t know if anyone in my family is very heavy

17. Does anyone in your family have diabetes? Circle all that apply.

Please answer for your daughter.

My daughter’s.............

a. None of the people listed below have diabetes
b. Mother
c. Father
d. Sister or brother
e. Grandmother on mother’s side
f. Grandfather on mother’s side
g. Grandmother on father’s side
h. Grandfather on father’s side
i. Aunt or uncle on mother’s side
j. Aunt or uncle on father’s side
k. Cousin on mother’s side
l. Cousin on father’s side
m. I don’t know if anyone in my family has diabetes
18. Does anyone in your family have high blood pressure? Circle all that apply.

Please answer for your daughter.

My daughter’s..........

a. None of the people listed below have high blood pressure  
b. Mother  
c. Father  
d. Sister or brother  
e. Grandmother on mother’s side  
f. Grandfather on mother’s side  
g. Grandmother on father’s side  
h. Grandfather on father’s side  
i. Aunt or uncle on mother’s side  
j. Aunt or uncle on father’s side  
k. I don’t know if anyone in my family has high blood pressure

19. Does anyone in your family have a history of heart problems? Circle all that apply.

Please answer for your daughter.

My daughter’s..........

a. None of the people listed below have heart disease  
b. Mother  
c. Father  
d. Sister or brother  
e. Grandmother on mother’s side  
f. Grandfather on mother’s side  
g. Grandmother on father’s side  
h. Grandfather on father’s side  
i. Aunt or uncle on mother’s side  
j. Aunt or uncle on father’s side  
k. I don’t know if anyone in my family has heart disease
Visit #1 Questionnaire for Parent

Study ID #: ________________

Developmental Health Questions

1. How old was your daughter when she first began to develop breasts? ____________

2. How old was your daughter when she first began to develop her pubic hair? ____________

3. How old was your daughter when she first began to develop hair under her arms? ____________

4. Was she taken to a doctor to be checked out for early puberty because she developed breasts, hair under her arms, or pubic hair too early? Circle yes or no.

   YES   NO

Thank you. You have finished answering all the questions.
Visit #1 Questionnaire for Child

Study ID #: ______________

Directions:
All questions to be asked to the child by a study physician or the study coordinator.

Read to Child:
You can choose if you want to have your mother and/or father in the room while you answer these questions. They can stay in the room or you can answer the questions alone with me (doctor or study coordinator).

We will keep your answers private.
No one will be mad if you want your mom and/or dad out of the room when you answer the questions.

Would you like your parent(s) in the room?

<table>
<thead>
<tr>
<th>Study Staff:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(circle one)</td>
<td></td>
</tr>
<tr>
<td>Parent(s) PRESENT</td>
<td>for administration of questionnaire</td>
</tr>
<tr>
<td>—or—</td>
<td></td>
</tr>
<tr>
<td>Parent(s) NOT PRESENT</td>
<td>for administration of questionnaire</td>
</tr>
</tbody>
</table>

Questionnaire Administered by: _____ (study staff initials)
Visit #1 Questionnaire for Child

Study ID #: ______________

Age Questions
1. How old are you?
   a. 10
   b. 11
   c. 12
   d. 13
   e. 14
   f. 15

2. What grade are you in?
   a. 4th grade
   b. 5th grade
   c. 6th grade
   d. 7th grade
   e. 8th grade
   f. 9th grade
   g. 10th grade
   h. 11th grade
   i. 12th grade

Menstrual and Birth Control History
3. Have you ever had a menstrual period (menstruation)?
   a. No, I have not started having periods (menstruating) yet.
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4. Have you ever used birth control?
   a. No.................................................................(skip to question #6)
   b. Yes

5. Which forms of birth control have you used? Circle all that apply.
   a. Birth control pills (the pill)
   b. Depo-Provera (the shot)
   c. Ortho Evra (the patch)
   d. Nuva Ring (the ring)
   e. Mirena (IUD)
   f. Some other method
   g. Not sure
Visit #1 Questionnaire for Child

Establishment of Regular Ovulation in Normal Menarche, Aim #2
PI: Nanette Santoro, MD
COMIRB Protocol #11-0551

Study ID #: ______________

Medical History

6. Do you have an eating disorder?
   a. I do not have an eating disorder
   b. I have Anorexia Nervosa
   c. I have Bulimia
   d. I am not sure

7. Have you ever been told by a doctor that you have a kidney or liver disease?
   a. Yes
   b. No
   c. Not sure

8. Do you have diabetes?
   a. Yes
   b. No
   c. I don’t know

9. Do you take Insulin shots every day?
   a. Yes
   b. No
   c. I don’t know

10. Do you have any chronic health conditions? (This means a health condition for which you need regular medication or doctor visits for treatment)
    a. Yes. Please write the name here: ____________________________
    b. No

Medication Questions

11. Have you received steroid medication (such as: Prednisone, Decadron, Hydrocortisone) for an illness over the past three months?
    a. Yes
    b. No
    c. I am not sure

12. Have you been on medicine for the treatment of cancer (chemotherapy) over the past three months?
    a. Yes
    b. No
    c. I am not sure

13. Have you taken prescription medication (not including Tylenol, Advil/Motrin or vitamins) over the past three months?
Visit #1 Questionnaire for Child

Study ID #: ____________________

a. Yes
b. No.................................................................(skip to question #15)
c. I am not sure.....................................................(skip to question #15)

14. Please write the names of any medicine you have taken over the past three months:

________________________________________

________________________________________

________________________________________

________________________________________

15. If you have taken any medicine not prescribed by a doctor that you or someone else got for you over the past three months please write the names here:

________________________________________

________________________________________

________________________________________

________________________________________

Developmental Health Questions

1. How old were you when you first began to develop breasts? _________

2. How old were you when you first began to develop your pubic hair? _________

3. How old were you when you first began to develop hair under your arms? _________

4. Were you taken to a doctor to be checked out for early puberty because you developed breasts, hair under your arms, or pubic hair too early? Circle yes or no.

YES NO
General Physical Exam

HEENT:

Neck:

Breasts:

Chest:

Cardiac:

Abdomen:

Pubic Hair:

Allergies:

Medications

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosage</th>
<th>Indication</th>
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<tbody>
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</table>

Physician Signature: _______________________________ Date: ___________
Safety Questionnaire

Study ID #: ________________

Phone Call/Visit: Treatment #1 Call Treatment #2 Call Visit #2 Post Study Follow-up Call
(circle one)

Most Common Side Effects:
1. Have you seen any rashes on your body? YES NO
2. Have you had any vaginal spotting (seen any blood in your underwear)? YES NO
3. Have you had any breast tenderness or tingling? YES NO

Rare:
4. Have you experienced any headaches or Migraine headaches? YES NO
5. Have you noticed any changes in mood? YES NO
6. Have you experienced any nausea or had the urge to vomit? YES NO
7. Have you had any leg swelling or pain? YES NO

Very Rare:
8. Have you started your period? YES NO
9. Have you noticed any breast development? YES NO

Very Rare but Serious:
10. Have you had trouble breathing or any shortness of breath? YES NO
11. Any belly/stomach pain? YES NO

Pregnancy:
12. Do you think you may be pregnant? YES NO

Any Other Concerns?

Details for any ‘YES’ answers above:

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

Form Completed by: ______ (Initials)

Version 2: 29-Apr-2011
Urine Collection Instructions & Log

Study ID #: ________________

You will be given a bag containing one box with tubes, one empty box, cups, a sheet of labels and a laundry marker pen. Place these along with the instructions in a convenient place, probably in or near your bathroom.

- As soon as you wake up in the morning (or the night before), select a tube and write the date on the label using one of the pens provided. If you lose the special pen, you can write the date on the label with a pencil.
- Use a paper cup and collect your first urine of the morning into the cup.
- Remove the cap from the tube for the day. Try to avoid spilling the glycerol (a harmless syrupy fluid) that is already in the tube as you pour urine into it. Fill the tubes up to the line marked on the tube.
- Screw the cap firmly onto the tube and wipe off any urine on the outside of the tube. Turn the tube upside down three times to mix the urine with the glycerol.
- Place the tube in the box in the freezer. Keep the capped tubes upright. If you are not at home some morning, refrigerate the urine specimens within 2 hours and freeze within 24 hours, if possible. Write in the log below “not cold” and write down about how long it was until you got the tubes into the freezer.
- If for any reason you miss a day, place the empty tube into the box in the freezer. If you forget your first urine, but remember your second urination of the morning, collect it anyway and record it in the log sheet that way. Also, if you are ill, have problems or want to tell us something, write that in the log below.

If you have any questions please contact Jennifer Lesh at 303-724-2046 or jennifer.lesh@ucdenver.edu.

<table>
<thead>
<tr>
<th>Study Day</th>
<th>Date</th>
<th>Did you wear the patches?</th>
<th>Notes: “not cold” “not first morning urine” “missed day” etc.</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td></td>
<td>YES NO</td>
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<td>2</td>
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<td>7</td>
<td></td>
<td>YES NO</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td>Take the patches off.</td>
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Version 2: 29-Apr-2011

Page 1 of 1
Puberty

Puberty is the name for the time when your body goes through changes and you begin to go from being a child to an adult. Your hormone levels will change, you will develop breasts, grow taller, and start your menstrual periods. Puberty usually starts between 8 and 13 years of age. During puberty, the same changes happen to all girls, but the time they happen is different for every girl. These changes are all part of becoming a woman. They are something to celebrate!

When the time is right, your body sends a signal (FSH, LH) from the pituitary gland in your brain to your ovaries for puberty to begin.

Breast development. Your breasts will start to grow. Your breasts will start as breast “buds”, small mounds beneath the nipple and areola. (The areola is the dark area surrounding your nipple.) One breast may start growing before the other, sometimes even 6 months before the other. In the beginning, they may hurt sometimes and be tender when they are touched. But this will go away as your breasts become rounder and fuller. The nipple and areola also darken. Many girls have breasts that develop unevenly: one breast may be bigger than the other. This is perfectly normal. Many women have one breast that is slightly larger than the other, but the difference in breast size usually decreases as your breasts develop. Young women may have different breast sizes because of differences in families, hormones, and weight. Rapid development of breasts can lead to spoke-like stretch marks, but these will lighten with time. Towards the end of puberty, you may also grow a small amount of hair around your areola.

You may need to start thinking about wearing a bra to support your breasts. Talk to your mother, an older sister, or an adult that you feel comfortable with about buying some bras.

Diagrams below show the 5 stages of breast development:
Puberty

Pubic and underarm hair. You will start to grow hair around your pubic area (around your vagina) and under your arms. This usually happens after you start to develop breasts, but for many girls, pubic hair starts first. You will probably get pubic hair before you get underarm hair. Underarm hair usually comes near the end of puberty. At first, you will probably just have a few fine hairs in your pubic area and under your arms. Late in puberty, the hair will become thicker and curlier. Some girls decide to shave the hair under their arms. There are no health reasons to do so, but some girls simply prefer not to have underarm hair. It is up to you if you want to shave. Talk to your mom or another adult that you feel comfortable talking to about this.

Diagrams below show the 5 stages of pubic hair development:

Growth spurt and body shape change. Most girls have a growth spurt the year before they get their menstrual period. Your feet and hands will usually be the first parts to grow, and then the rest of your body will follow. After you get your first period, you will grow more slowly. But you will probably grow another 1 or 2 inches after your first period. During puberty, your hips will get wider as your waist gets smaller. You will develop a healthy, curvy shape. Talk to your health care provider if you are not growing and changing by age 13. It’s important to get check-ups during puberty to make sure that your height and weight are normal.

Vaginal discharge. Most girls notice a yellow or white stain in the crotch of their underpants as they go through puberty. This is a normal fluid that helps clean and moisten your vagina. However, if you have itching, odor, or irritation around your vagina, this could mean that you have an infection. If you have any of these symptoms, talk to your health care provider. You will usually get your period a year after you first have discharge from your vagina.

Skin. Your skin may get oilier. You may get some pimples and acne. This is because of more hormones and oil glands that become more active during puberty. You should be washing your skin at least once daily with soap and warm water. Don’t scrub too hard because this can irritate your skin and cause even more acne. Wash your hair regularly and keep your face and hands clean. You can treat acne with medications that you can buy in a drugstore, or get from your primary care clinician or a dermatologist (a doctor that treats skin problems) if the problem is more serious. Birth control pills that you take by mouth often make acne better.

Sweat/Perspiration. Your sweat glands will become more active during puberty. This can cause perspiration odor. This is a good time to go shopping for deodorant, to help fight the odor.

Menstruation. You will also start getting your monthly period. Most girls start getting their periods about 2 and a half years after they first start developing breasts, some girls may start just 1 year after breast development, and other girls often start 3-4 years after breast development. Most girls have their first period between the ages of 12 and 13, but some girls start as early as age 9, and others as late as 15 or 16.
Written by the CYWHA Staff at Children's Hospital Boston

Updated: 4/21/2010

Related Guides:

Menstrual Periods
When you reach puberty and you are becoming a woman, your ovaries make hormones (especially estrogen) that cause breast development and menstrual periods...

Breast Health
Your breasts start growing when you begin puberty. Puberty is the name for the time when your body goes through changes and you begin to go from being a child to an adult...

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When Your Child Is Close to Puberty

What is puberty?

Puberty is the time in life when a young person starts to become sexually mature.

In girls, puberty may start as early as 8 years of age, but it usually starts around 11 years of age. In boys, it begins around 12 years as age, but may start as early as 9 years of age. This is a process that goes on for several years. Most girls are physically mature by about 14 years of age. Boys mature a year or two later.

What are the first signs of puberty in boys and girls?

The first sign of puberty in most girls is breast development. The first sign of puberty in most boys is an increase in the size of the testicles.

Does sexual development have a typical pattern?

Yes. In girls, breasts develop first. Then, hair starts growing in the pubic area. Next, hair starts growing in the armpits. In girls, acne usually starts around 13 years of age. Menstruation (the period) usually happens last.

In boys, the testicles and the penis get bigger first. Then hair grows in the pubic area and the armpits. A small amount of breast tissue might develop at this time. The voice becomes deeper. Muscles grow. Last, acne and facial hair show up.

Does sexual development always follow the same pattern?

No. Some children can have different patterns. Some girls develop breasts at a very young age but have no other signs of sexual development. A few children have pubic and armpit hair long before other signs of sexual growth. These changes in pattern usually don't mean the child has a problem, but it's a good idea to visit your doctor to find out for sure.
What is early puberty? What causes it?

You may want to visit your doctor if a young girl:

- Develops breasts and pubic hair before 8 years of age.

You may want to visit your doctor if a young boy:

- Has an increase in testicle size and penis length before 9 years of age.

Early puberty is sometimes called precocious or premature puberty. In most cases, early puberty is just a variation of normal puberty. In a few cases, there may be a medical reason for early puberty.

What is delayed puberty? What causes it?

Puberty may be late in girls who have the following signs:

- No development of breast tissue by age 14
- No periods for 5 years or more after the first appearance of breast tissue

Puberty may be late in boys who have the following signs:

- No testicle development by age 14
- Development of the male organs isn't complete by 5 years after they first start to develop.

Sometimes a medical reason causes delayed puberty, but sometimes not. For example, malnutrition (not eating enough of the right kinds of food) can cause delayed puberty.

Do early and late puberty run in families?

Both early and late puberty can run in families. There can be other causes, too.

How will my doctor know what is causing the change in puberty pattern?

Your doctor will talk to you and your child. Then your child will have a physical exam. The doctor might suspect a cause for the puberty variation and order some tests. Sometimes the cause can’t be found even after several tests.

These are some tests your doctor might order for your child:

- Blood tests to check hormone levels
- An x-ray of the wrist to see if bone growth is normal
- A CT or MRI scan (special pictures) of the head to look for a tumor or brain injury
- Chromosome (gene) studies
Are early and late puberty treated?

In most children, no cause is found. It's just a variation of normal puberty. No treatment is needed. In some children, a medical cause is found and treated. For example, if the reason for late puberty is lack of hormones, hormone shots can help.

What can I do to help my child?

The way children see their own body has a lot to do with their self-esteem. It's important to let children know they're OK the way they are and that you love them that way. You can let your child know that he or she is normal (when the tests are normal). You can tell your child that you'll help him or her with any problems (if the tests show a problem). If you need help or if you think your child may need counseling, talk to your family doctor.

This handout provides a general overview on this topic and may not apply to everyone. To find out if this handout applies to you and to get more information on this subject, talk to your family doctor.

Visit familydoctor.org for information on this and many other health-related topics.

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1. NAME AND ADDRESS OF INVESTIGATOR
Nanette Santoro, MD
University of Colorado Denver, Dept. of Ob/Gyn
Mail Stop B 198-1, Academic Office 1
12631 East 17th Avenue, Room 4010
Aurora, CO 80045

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 ATTACHED.

☐ 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.

University of Colorado Denver School of Medicine, Anschutz Medical Campus, 13001 East 17th Place, Aurora, CO 80045
The Children's Hospital Pediatric Clinical Translational Research Center, Mail Stop B 218, 13123 E 16th Ave, Aurora, CO 80045

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

NONE

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

Colorado Multiple IRB (COMIRB)
Mail Stop F 490
13001 E. 17th Place, Room N3214
Aurora, CO 80045

6. NAMES OF THE SUBINVESTIGATORS (e.g., research fellows, residents, associates) WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S).

Alex Polotsky, MD MS
Andrew Bradford, PhD
Jennifer Lesh, BA

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

Establishment of Regular Ovulation in Normal Menarche, Aim #2
8. ATTACH THE FOLLOWING CLINICAL PROTOCOL INFORMATION:

☐ 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 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 312.88.

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. Attach a separate page if additional space is needed.

2. Attach curriculum vitae or other statement of qualifications as described in Section 2.

3. Attach protocol outline as described in Section 8.

4. Sign and date below.

5. FORWARD THE COMPLETED FORM AND ATTACHMENTS 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. SIGNATURE OF INVESTIGATOR

11. DATE

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

Public reporting burden for this collection of information is estimated to average 100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

"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 control number."

Please DO NOT RETURN this application to this address.