UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Pilot Randomized Controlled Trial of Spironolactone in Women With Nonalcoholic Steatohepatitis (NASH)

This is a clinical trial, a type of research study. Your study doctor, Dr. Monika Sarkar, M.D., or her study staff from the UCSF Department of Gastroenterology/Hepatology, will explain the clinical trial to you.

Clinical trials include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are a woman with liver disease due to Non-Alcoholic Steatohepatitis (NASH). NASH is a form of liver damage that occurs when fat builds up in the liver and causes inflammation and scarring (fibrosis).

Why is this study being done?

The purpose of this study is to find out if the medication, spironolactone, can help to improve NASH or the conditions that are commonly associated with NASH, including high cholesterol or abdominal fat and whether the treatment is easy to tolerate. The results of this study will help planning of future studies with this medication. Spironolactone is a commonly used medication and approved drug in women to treat high testosterone levels, and data in animal models and humans support a role of testosterone in promoting metabolic disease including fatty liver. Spironolactone is not FDA approved for the potential treatment of fatty liver disease, NASH, however it is FDA approved for other conditions.

Who pays for this study?

This research is being funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a branch of the National Institutes of Health (NIH). The NIDDK conducts, supports, and coordinates research on many of the most serious diseases affecting public health.

How many people will take part in this study?

About 30 women will take part in this study at UCSF.

What will happen if I take part in this research study?

If you decide to take part in this research study, you will need to complete a screening visit to see if you are eligible to participate. Once the study doctor determines you are eligible, you will be asked to come back to the clinic 4 times over a 6-month period (for the Baseline/Day 1 Visit, the Month 1 Visit, the Month 3 Visit, and the Month 6 Visit). After the 6-month period on the study, you will have the option to indicate whether or not you wish to continue to follow up with the study team up

till 12 months. If you wish to extend the study period, you will be asked to follow up in-person at Month 9 and Month 12. You will be asked for a Follow-Up call within three months after you finish taking the study drug.

In cases where the study procedure results may seem abnormal, for safety reasons your study doctor may ask you to make an unscheduled visit to the clinic to perform additional procedures or tests to confirm or clarify the result. Signing this Informed Consent Form allows for additional safety procedures to be performed when appropriate. Any additional procedures will be discussed with you in advance.

Before you begin the main part of the study...

You will need to have the following exams, tests or procedures to find out if you can be in the main part of the study.

- A liver biopsy done previously. This liver biopsy would have been performed as part of your standard of care for NASH and must have been performed prior to Day 1.
- Review and sign this Informed Consent Form.
- Review prior and current medications that you are taking.
- Review your medical history and how well you have been feeling.
- Perform a physical exam.
- Vitals signs (blood pressure, heart rate), height and weight.
- Obtain some samples of your blood to check your general health.
- If you are a woman who can have children, collect a sample of your urine for pregnancy testing.

During the main part of the study...

If the exams, tests and procedures show that you are eligible to participate in the main part of the study, then you will need the following tests and procedures that are being done to see how the study is affecting your body.

- At Baseline/Day 1, you will be "randomized" into a group to either take 100 mg of spironolactone daily or to take placebo. Randomization means that you are put into a group by chance. Neither you nor your doctor can choose the group you will be in. You will have a 66.7% chance of receiving spironolactone and a 33.3% chance of receiving placebo.

  - Group A: 20 patients, spironolactone 100 mg, once daily
  - Group B: 10 patients, placebo, an inactive substance that contains no real study drug, once daily

During the study, neither you nor your doctor will know which study treatment you are receiving even if you stop taking the study drug. However, in an emergency, your study doctor can find out if you are taking the placebo or the study drug, spironolactone.

Regardless of which group you are assigned to, you will be asked to take the study drug capsules (spironolactone or placebo) at approximately the same time every day for the duration of the

study. You will be advised to take the capsules whole with water, with or without food. On days when you have study visits, you will be asked to bring the bottles of study drug with you to the study site.

Study Procedures for the Treatment Phase

- Limited physical exam depending on any symptoms you are experiencing.
- Vital signs (resting blood pressure, pulse) and weight.
- Measure your waist circumference.
- Review changes in your health since last visit.
- Review medications you are taking.
- Draw some samples of your blood for safety monitoring and to check your general health, cholesterol, glucose, insulin levels, and liver health.
- Draw samples of your blood to measure your sex hormone levels.
- If you are a woman who can have children, collect a sample of your urine for pregnancy testing.
- Provision of home pregnancy test kits (only for women who can have children, every visit from Day 1 to End of Study/Treatment)
- Record result of home pregnancy tests over the phone with coordinator every 4 weeks between visits (only for women who can have children, from Month 1 to End of Study/Treatment)
- Scan of the liver: MRE and MRI-PDFF (Day 1, Month 6, and Month 12 [if you opt to extend the study period to 12 months])
- Repeat liver biopsy to assess for effects of the treatment (End of Study/Treatment only and optional).
- Review the amount of study drug you have taken since the last visit (except at Day 1).
- Provide you with the study drug for each period and instruct you to take 1 capsule daily with a glass of water.
- Collect all unused study drug.

Table 1 below lists the procedures or tests that the study doctor will perform at each study visit during the study. An "X" in the column tells you that the procedure will be done during that visit. If the information in the table below is not clear to you, please ask the study doctor or her study staff to explain it to you.

When you are finished receiving study drug...

After you complete the treatment phase, you will complete a final Follow-Up visit within 3 months of the last dose of study drug. For the Follow-up Visit, the following will be conducted:

- Review changes in your health since last visit.
- Review medications you are taking.

Table 1

	Screening	Baseline/ Day 1	Month 1	Month 3	Month 6 End of Study/ Treatment	Month 9*	Month 12* End of Study/ Treatment	Follow-Up within 3 months of EOS/EOT
	Visit 1	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	
Obtain informed consent	X							
Review your medical history	X							
Review medications you are taking	X	X	X	X	X	X	X	X
Perform complete physical exam	X							
Perform physical exam depending on your symptoms			X	X	X	X	X	
Measure your vital signs (blood pressure, heart rate)	X		X	X	X	X	X	
Measure your weight and height	X[a]		X	X	X	X	X	
Measure your waist circumference	X				X		X	
Review your general health (side effects and illnesses)		X	X	X	X	X	X	X
Draw samples of your blood for to check your general health, liver health, cholesterol, glucose, and insulin levels	X		X	X	X	X	X	
Draw samples of your blood to check your sex hormone levels	X				X		X	
If you are a female who can have children, collect a sample of your urine for pregnancy testing	X[b]		X	X	X	X	X	
Collect a small liver sample (biopsy)	X[c]				X*		X*	
Scan your liver: MRI-PDFF and MRE		X			X		X	
Give you study drug and instructions on how to take it		X	X	X	X	X	X	
Review the amount of study drug you have taken and collect unused			X	X	X	X	X	

a Height only measured at Screening
b In addition, home pregnancy tests are to be performed by women who can have children every 4 weeks from Day 1 until End of Study/Treatment
c Performed prior to screening as part of your standard of care for NASH
*Optional visits/procedures

- **Study location:** All study procedures will be done at various UCSF sites. Study visits will be done in the UCSF Liver Clinic at 350 Parnassus Ave. Suite 300 and the Ambulatory Care Center at 400 Parnassus Ave. San Francisco, CA 94143. The liver biopsies will be done in the Peri-Procedural Unit (PPU) on the 6th Floor of Moffitt Hospital at 505 Parnassus Ave. MRE and MRI-PDFF will be done at the China Basin Imaging Center at Berry St., Suite 190, Lobby 6, San Francisco, CA 94107.

- **Blood drawing (venipuncture):** At each study visit a blood sample will be drawn by inserting a needle into a vein in your arm. Each sample will be approximately 1-3 tablespoons; a total of about 4 tablespoons will be drawn for each visit.

- **Liver scan - MRI:** At Baseline/Day 1, Month 6, and Month 12 (if opt to extend study period) you will have two types of Magnetic Resonance Imaging (MRI) exams, a MRE (Magnetic Resonance Elastography) and a MRI-PDFF (Magnetic Resonance Imaging-Proton Density Fat Fraction). All the MRI measurements for both MRE and MRI-PDFF will be taken as part of one time in the MRI machine. Prior to the MRI scan you will be asked to remove all metal from your clothing, pockets, shoes, and person. You will be asked to wear clothing compatible with the MRI environment. You will be provided with earplugs or headphones that you must wear during the entire scan. Protective padding will be placed between your body and the inner walls of the scanner. You will lie down on a narrow bed that will then be placed in a tunnel that is 6 feet long by 22 inches wide and open at each end. You will need to lie there quietly for 50 to 60 minutes. During the scan you will hear loud sounds that are a normal part of the scan.
    - **MRE (Magnetic Resonance Elastography):** A paddle attachment will be wrapped around your waist and sound waves will be sent through your body while you are inside the MRI unit. You will not feel the magnetic field of the MRI machine. You may feel vibrations from the paddle attachment on your skin. You will be asked to hold your breath at least four times during the MRE scan. Each breath hold will last about 15- 20 seconds.
    - **MRI-PDFF (Magnetic Resonance Imaging-Proton Density Fat Fraction):** Once inside the machine, a magnetic field will be directed at your body. You will not feel the magnetic field of the MRI machine. You will be asked to hold your breath at least once during the MRI-PDFF scan. The breath hold will last about 15-20 seconds.

- **Liver Biopsy (optional End of Study procedure):**
  During the biopsy, the doctor will make a small incision on your upper abdomen and insert a needle to take a small sample of your liver. It will be a brief procedure to collect the sample. After the biopsy, you will be asked to lie in bed for several hours, and you should not drive for about 8 hours. You should also avoid any strenuous activity for a few days as per your doctor's recommendation.

    - A numbing medicine (local anesthetic) may be used in the area in which the biopsy will take place and/or you may be given pain medicine. You may feel a brief sting or burn when the numbing medicine goes in your skin. When the biopsy needle is inserted, you may feel a deep pressure and a dull or sharp pain during this brief procedure.

- After the numbing medicine wears off, you may feel a dull pain in your right shoulder region. This is called 'referred pain' and generally goes away in about 12 hours. Talk to your doctor before you take a non-prescription medicine for the pain or to ask for prescription pain medicine, if needed.

- A small amount of bleeding from the biopsy site may be expected. Ask your doctor how much drainage to expect.

- If a biopsy procedure other than listed above is performed, the investigator will review the procedure and discuss with you regarding potential risks.

How long will I be in the study?

You will be asked to take the study drug for 6 months. You will have the option to take the study drug for 12 months. After you are finished taking the study drug, the study doctor will ask you for a follow-up within three months.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. She will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the spironolactone can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you. If you decide to leave the research study, you are strongly urged to return to the Study Doctor for an End of Treatment Visit and the Follow-Up Visit, which should occur within three months of End of Treatment.

The study doctor may stop you from taking part in this study at any time if she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. You will be watched carefully for any side effects and asked about side effects at each of the visits. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking spironolactone. In some cases, side effects can be serious, long lasting, or may never go away. However, doctors don't know all the side effects that may happen. Some medications may increase the potassium in your blood when taken in combination with spironolactone. Your medications will be reviewed by the study doctor to ensure there are no known combinatory effects with spironolactone prior to you beginning the medication.

You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and side effects related to spironolactone include those which are:

Likely

- Increased urination

Less Likely

- Breast tenderness
- Tiredness
- Headache
- Dizziness
- Lightheadedness
- Diarrhea
- Cramping
- Nausea
- Vomiting
- Fever
- Confusion

Rare but serious

- Fluid or electrolyte imbalance which may cause symptoms such as dry mouth, excessive thirstiness, weakness, fatigue, drowsiness, muscle pain or cramps, fast heart beat, nausea or vomiting.
- Spironolactone has not been studied in pregnant women, but studies with animals have shown it is possible spironolactone could cause abnormal development or birth defects in the offspring of women who become pregnant while taking spironolactone. There have been no studies showing these birth defects in humans. However, it is important to follow the study's contraceptive guidance carefully. It is expected this potential risk would be avoided if spironolactone is stopped within 6 weeks after becoming pregnant.

- **Randomization risks:** You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

- **Placebo risks:** If you are in the group that receives placebo, your condition will go without the active (study) treatment for 6 months. If you opt to extend the study period, your condition will go without the active treatment for 12 months.

- **Blood drawing (venipuncture) risks:** Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.

- **MRI risks:** Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which in the process could possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. If

you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI.

Having an MRI may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear headphones. At times during the test, you may be asked to hold your breath for a while, which can be uncomfortable.

Because the risks to a fetus from MRI are unknown, pregnant women must not participate in this study.

- **Liver biopsy risks (optional End of Study procedure):** You may feel a brief sting or burn when the numbing medicine goes in your skin. You may feel a deep pressure and a dull or sharp pain during this brief procedure. After the numbing medicine wears off, you may feel a dull pain in your right shoulder region. Serious problems from undergoing liver biopsy are rare. Problems may include (but may not be limited to):
    - Bleeding, which may need blood transfusions or surgery to correct,
    - A collapsed lung,
    - Injury to the intestines, blood vessels, nerves, gallbladder or kidney,
    - Infection in the belly.

- **Reproductive risks:** You should not become pregnant while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important to understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. Female patients who are able to become pregnant must use at least one method of birth control throughout the study period. Acceptable birth control methods include:
    - Condom with spermicide;
    - Diaphragm with spermicide;
    - Intrauterine device;
    - Bilateral tubal ligation
    - Vasectomy in sole male partner;
    - Contraceptive pill, patch, intramuscular implant or injection;
    - Abstinence if it is your preferred and usual lifestyle.

- If you are not sure about your birth control methods, please talk to the study doctor. If you become pregnant during the study, you should stop taking the study drug immediately and contact the study doctor right away. If this happens, your pregnancy will be followed to its outcome (for example, until you have your baby). If you have a baby, the baby's health will be followed up by the study doctor. Neither the clinic nor the study doctor will be responsible for the cost of any medical care related to the pregnancy, or for your child's care.

- **Unknown Risks:** The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

- For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

If you are in the group that receives spironolactone and it proves to treat your condition, you may benefit from participating in the study, but this cannot be guaranteed.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for NASH without being in a study.
- Taking part in another study.
- Getting no treatment.

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The University of California
- The Food and Drug Administration (FDA), involved in keeping research safe for people.

What are the costs of taking part in this study?

Two types of procedures will be done during this study. Some are part of your standard medical care, such as the liver biopsy done prior to the screening visit performed as routine care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you

are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer. The costs related to the repeat biopsy done at the end of the study will be covered by the study.

The study doctor will provide the study drug, spironolactone or placebo at no cost to you.

Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will be paid $175 for taking part in this study if you complete all of the study visits and procedures. You will be paid $20 after each study visit you complete and an additional $75 after the end of study liver biopsy. If you are traveling from outside of San Francisco, you will be paid up to $50 for mileage and toll for each visit.

You will also receive parking stickers to cover cost of parking in the UCSF Parnassus garage. Parking is free at the UCSF Imaging Center at China Basin.

You will receive payment after each visit in the form of a check mailed to your home. You should receive the check four to six weeks after each visit. You must give the researchers your home address and Social Security number so the check can be processed.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. Monika Sarkar, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call her at 415-502-2656.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor, Dr. Monika Sarkar, at 415-502-2656.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

OPTIONAL FUTURE RESEARCH

Please note: This section of the informed consent form is about optional research studies that are being done with people who are taking part in the main study. You may take part in these optional studies if you want to. You can still be a part of the main study even if you say "no" to taking part in the optional studies. You can say "yes" or "no".

You are being asked to take part in an optional substudy to the main study. The purpose of this substudy is to collect blood and liver tissue samples that will be used to conduct future studies investigating the link between reproductive health in women and liver disease.

Your blood and liver tissue samples will be stored at the UCSF Clinical Research Services Moffitt site in a specimen bank to be used for future research to learn more about your medical condition and other medical problems. Once collected, you may be called from time to time to update information on your health that is necessary to keep the blood/data bank current.

We may give your specimens and certain medical information about you (for example, diagnosis, blood pressure, age if less than 85) to other scientists or companies not at UCSF, including to a public or controlled access government health research database, but we will not give them your name, address, phone number, or any other information that would identify you. Research results from these studies will not be returned to you.

Optional Blood Sampling and Genetic Testing

Procedures

If you decide to take part you will have additional blood (approximately 2 tablespoons) drawn at the same time samples are being taken for each visit.

The additional blood sample will be used for laboratory tests. Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if we use the specimen for

genetic research, we will not put the results in your medical records. The research will not change the care you receive. Your specimen and any information about you will be kept until it is used up or destroyed. It may be used to develop new drugs, tests, treatments or products. In some instances these may have potential commercial value. In some instances these may have potential commercial value, but you will not share in that benefit. Your personal health information cannot be used for additional research without additional approval from either you or a review committee.

Alternative to participation

You may choose not to participate in this sub study without affecting your participation in the main study, your medical care, or the relationship with your Study Doctor.

You may at any time contact the researchers in writing to the attention of: Monika Sarkar, MD, 513 Parnassus Avenue, S357, San Francisco, CA 94143, to ask that your samples be withdrawn from research use, and any identifiable samples still in their possession will be destroyed. However, if any research has already been done using portions of your specimens, the data will be kept and analyzed as part of those research studies.

Risks and inconveniences

Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health.

To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk.

Although your name will not be with your samples, it will have other facts about you such as age, race/ethnicity, and reproductive history. These facts are important because they will help us learn if the factors that cause liver disease in women occur or get worse based on these facts.

Thus it is possible that study findings could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.

Benefits

The benefits of this research include learning more about what causes liver disease in women and about other diseases, how to prevent them, and how to treat them.

Making Your Choice

Please read the sentence below and think about your choice. After reading the sentence, put your initials by the "Yes" or "No" box. If you have any questions, please talk to your doctor, or call our research review board at the IRB's phone number.

No matter what you decide to do, it will not affect your care.

_____☐ Yes, I agree to the collection of additional blood at each visit for future research which may include genetic testing.

_____☐ No, I do not agree to the collection of additional blood at each visit for future research which may include genetic testing.

Optional Storage of Liver Biopsy Tissue

Procedures

If you participate in the main study, you may have a liver biopsy at the End of Study/ End of Treatment visit. Your doctor will remove some tissue to do some tests. The results of these tests will be given to you by your doctor.

We would like to keep some of the tissue that is left over for future research. If you agree, this tissue will be kept and may be used in research to learn more liver disease or other diseases. The research that may be done with your tissue is not designed specifically to help you. It might help people in the future.

Reports about research done with your tissue will not be given to you. These reports will not be put in your health record. The research will not have an effect on your care.

Alternative to participation

The choice to let us keep the left over tissue for future research is up to you. No matter what you decide to do, it will not affect your care.

You may at any time contact the researchers in writing to the attention of: Monika Sarkar, MD, 513 Parnassus Avenue, S357, San Francisco, CA 94143, to ask that your tissue be withdrawn from research use. Then any tissue that remains will no longer be used for research. However, if any research has already been done using portions of your tissue, the data will be kept and analyzed as part of those research studies.

In the future, people who do research may need to know more about your health. While we may give them reports about your health, we will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Your tissue may be used for genetic research. The results will not be put in your health records. Your tissue will be used only for research and will not be sold. The research done with your tissue may help to develop new products in the future.

Risks and inconveniences

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

Benefits

The benefits of research using tissue include learning more about what causes liver disease in women and about other diseases, how to prevent them, and how to treat them.

Making Your Choice

Please read the sentence below and think about your choice. After reading the sentence, put your initials by the "Yes" or "No" box. If you have any questions, please talk to your doctor, or call our research review board at the IRB's phone number.

No matter what you decide to do, it will not affect your care.

_____☐ Yes, my tissue may be kept for use in future research which may include genetic testing.

_____☐ No, I do not want my tissue to be kept for use in future research which may include genetic research.

Optional Follow-Ups with the Study Team

Procedures

If you participate in the main study, you may have the option to extend your time on the study drug to 12 months. If you choose to be on the study medication for 12 months, we will complete additional in-person follow-ups at Month 9 and Month 12. Month 12 will be your End of Study/Treatment visit.

Alternative to participation

You may choose not to participate in this sub study without affecting your participation in the main study, your medical care, or the relationship with your Study Doctor.

Risks and inconveniences

Participating in this sub study could inconvenience you. There will be two additional visits (at Month 9 and Month 12) where you need to travel to the study site. Discomfort may be associated with additional procedures.

Benefits

If you are in the group that receives spironolactone and it proves to treat your condition, you may benefit from participating in the sub study, but this cannot be guaranteed.

Making Your Choice

Please read the sentence below and think about your choice. After reading the sentence, put your initials by the "Yes" or "No" box. If you have any questions, please talk to your doctor, or call our research review board at the IRB's phone number.

No matter what you decide to do, it will not affect your care.

_____☐ Yes, I wish to extend the study period to 12 months.

_____☐ No, I do not wish to extend the study period to 12 months.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____	_____
Date	Participant's Signature for Consent
_____	_____
Date	Person Obtaining Consent