Principal Investigator: **Maureen Leehey, MD**
COMIRB No: **17-2318**
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Study Title: **A randomized, double blind, placebo-controlled paralleled study of tolerability and efficacy of Cannabidiol (CBD) on motor symptoms in Parkinson's disease**

Randomized controlled Study

Some people in this study may have a medical condition or a disability that does not allow them to make important decisions for themselves. If you have been asked to decide for someone else whether they should be in this study, please read this consent form carefully.

In this form, we use the words "you" and "your." If you are reading this form and deciding for someone else, the words 'you' and 'your' refer to that other person, not to you.

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

Cannabis, which is marijuana, is composed of many substances. Cannabidiol (CBD) is one of these substances. CBD may be helpful in treating the symptoms of Parkinson's Disease (PD). This study plans to learn more about how well CBD is tolerated and works to treat symptoms of PD.

You are being asked to be in this research study because you have Parkinson's Disease and related motor symptoms.

Other people in this study

Up to 75 people from your area will participate in the study.

What happens if I join this study?

In this study, a placebo or CBD cannabis extract oral solution with 59.3% CBD and 1.96% THC (~30:1 CBD:THC) from National Institute on Drug Abuse (NIDA) will be used. The CBD cannabis extract oral solution is an investigational drug and has not been approved for use by the FDA, however it is currently being used in FDA-approved research studies.

The CBD cannabis extract oral solution will be in a sesame oil formulation, 100 mg/mL of CBD. The placebo is a liquid that looks and tastes like the CBD cannabis extract oral solution but does not

contain the active ingredient of CBD. You will ingest the liquid by mouth at a low dose over the course of about 2-3 weeks and participants will be closely monitored for side effects at office visits. In this form, the term “study drug” is used to refer to both CBD Cannabis extract oral solution and placebo.

This study will have 2 different groups (CBD cannabis extract oral solution group and placebo group) of research subjects like you. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. You will receive study drug (CBD cannabis extract oral solution or placebo) for 2-3 weeks treatment period. You will start to take study drug at a low dose (1.25 mg/kg/day) of CBD once a day on day 1 and keep this low dose for 3-4 days (day 1-4). On day 4 or 5, you will start to take a high dose (2.5 mg/kg/day) twice a day for 10 (up to 14) days.

You will not know which treatment group you are in. Neither will your study doctor. This information needs to be kept secret so that the study is based on scientific results, not on peoples’ opinions. However, we can give this information out if you have an emergency. If you are in an emergency, make sure you tell the emergency staff about this study. They can contact us, and we will give them all relevant information.

If you join the study, you will come into the Clinical Translational Research Center at the University of Colorado Anschutz Medical Campus for 7 visits over the course of about 8 weeks. You will take study drug daily for about 2-3 weeks. The visits are a screening visit, baseline visit (study drug is started),two dose assessment visits, and a follow up safety visit. Below is a detailed description of what will be done at each visit and between visits.

If you join the study you are instructed to not take any form of cannabis other than the cannabis that is supplied as part of the study. Your blood and urine is checked at the first two visits, before you are given study drug. If the testing is positive for cannabis at one of these visits, you may return 14 days later for a repeat test. If that test is positive then you will not be included in the study.

Screening Visit

The purpose of this visit is to determine if you are eligible to participate in this study. This visit will take approximately 4 hours. After you discuss the study with the doctor and sign this consent form, the following will be done:

- Collection of medical history, medication and demographic information
- Vital signs
- Physical exam
- Evaluation of your PD symptoms
- Tests/questionnaires about your thinking/memory skills, health, mood, and sleeping habits, compulsivity, mental health concerns (if any)
- Questionnaires about drug, alcohol, and tobacco use
- Blood draw for laboratory tests (and pregnancy test for females)
- Blood draw for cannabis test
- Urine collection for urinalysis
- ECG (a recording of electrical activity of your heart)
- Tremor measure device dispatched and instruction

- You will need to measure your tremor with the dispatched device at home for 2 days after screening visit, and 3 days before baseline visit, twice a day (2 hours after breakfast dose and 2 hours after dinner dose), 90 seconds each measurement.

If possible, some of the above procedures may be done remotely, through a Zoom call after on-site screening visit.

Baseline Visit

If the study doctor determines that you qualify for the study based on the results from the screening visit, you will be asked to come in for a baseline visit within 4 weeks of the screening visit. You will also be reminded to measure your tremor for 3 consecutive days before baseline visit, twice a day (2 hours after breakfast dose and 2 hours after dinner dose), 90 seconds each measurement. This visit will take approximately 3-4 hours. The following will be done:

- Collection of medication information
- Vital signs
- Brief physical exam
- Evaluation of your PD symptoms
- Tests/questionnaires about your health, cognitive function, alertness, sleeping habits, mood, fatigue, pain, bladder function, skin, and quality of life
- Urine drug test
- Urine pregnancy test (for females)
- Blood draw for laboratory tests (only for some patients)
- Study drug will be dispensed and you will receive instructions about how to take the drug at home. This includes a diary on which you will record information each day about taking the medication, talking with study staff and any good or bad effects you notice
- You will start with a low dose (1.25 mg/kg/day) of CBD which will be taken in the clinic after the cognitive function test and MDS-UPDRS evaluation. You will need to stay for two hours after this dose so that study staff can monitor you
- Urine cups will be provided with instructions
- Tremor data collected and reviewed
- Take a picture of your central face and the photo will be reviewed by dermatologists for seborrheic dermatitis evaluation

If possible, some of the above procedures may be done remotely, through a Zoom call

Days 1-14 (+4) Treatment Period: at home

For the next 14 days or so, you will take the study drug at home every day as instructed by the study doctor and record information in the diary. You should take the study drug at about the same times every day: 30-60 minutes before breakfast, once a day for the first 4 days, and twice a day, 30-60 minutes before breakfast, and 30-60 minutes before dinner, minimum of six hours apart, for the rest

of the treatment period (10 /+4 days). You could take the study drug with a small amount of food as needed if you experience nausea. You will take study drug at a low dose (1.25 mg/kg/day) once a day for the first 3-4 days, and on day 4 or 5, switch to a higher dose (2.5 mg/kg/day) twice a day for 10 (up to 14) days. You will also be reminded to measure your tremor for 3 consecutive days before each dose assessment visit, twice a day (2 hours after breakfast dose and 2 hours after dinner dose), 90 seconds each measurement.

1.25 mg/kg/day dose assessment visit: in clinic

After you have taken the 1.25 mg/kg/day of study drug for 3-4 days you will return to the clinic. On the day of this visit you do not take the study drug until you arrive at clinic and the staff asks you to take it. You need to bring all used, partially used and not used study drug with you to the visit. This visit will take approximately 3.5 hours. The following will be done:

- Take the study drug and you have vital signs checked 1 hour later. At 3 hours after taking the study drug tremors are checked and your blood drawn for laboratory tests and to check the level of study drug
- Collection of medication information
- Collection of changes to medical history and side effects
- Vital signs
- Physical exam
- Evaluation of your PD symptoms
- Tests/questionnaires about your thinking/memory skills, health, mood, bladder function, non-motor symptoms, quality of life, pain, fatigue, and sleeping habits
- Tremor measured
- Blood draw for laboratory tests
- ECG (a recording of electrical activity of your heart)
- Urine pregnancy test (for females)
- Collect urine in the morning and bring it to the clinic visit
- Urine collection for urine analysis and laboratory tests

After you have taken 2.5 mg/kg/day of study drug for 3-5 days you will be reminded to complete questionnaires about your health, mood, quality of life, and sleeping habits at home.

2.5 mg/kg/day Dose Assessment visit, End of Treatment Period: in clinic

After you have taken the 2.5 mg/kg/day of study drug for 10 (+4) days you will return to the clinic. On the day of this visit you do not take the study drug until you arrive at clinic and the staff asks you to take it. You need to bring all used, partially used and not used study drug with you to this visit. This visit will take approximately 4 hours. The following will be done:

- Take the study drug and you have vital signs checked 1 hour later. Tremors checked 2 hours later. At 3 hours after taking the study drug vital signs are checked again and your blood drawn for laboratory tests and to check the level of study drug
- Collection of medication information
- Collection of changes to medical history and side effects
- Collection of your leftover study drug

- Vital signs
- Physical exam
- Evaluation of your PD symptoms
- Tests/questionnaires about your thinking/memory skills, health, mood, bladder function, non-motor symptoms, quality of life, pain, fatigue, and sleeping habits
- Tremor measured
- Blood draw for laboratory tests
- ECG (a recording of electrical activity of your heart)
- Urine pregnancy test (for females)
- Collect urine in the morning and bring it to the clinic visit
- Urine collection for urine analysis and laboratory tests
- Seborrheic dermatitis evaluation

Safety follow-up

About 3 and 7 days after the Final Dose Assessment Visit, study staff will call you on the phone and will ask you about your possible signs of withdrawal, your medications, and how you are doing.

About 2 weeks after the Final Dose Assessment Visit, you will return to the clinic. This visit will take approximately 2 hours. The following will be done:

- Collection of medication information
- Collection of changes to medical history and side effects
- Vital signs
- Physical exam
- Evaluation of your PD symptoms
- Tests/questionnaires about your health, mood, and sleeping habits
- Blood draw for laboratory tests (if your test results have changed significantly during the study)
- Blood draw for cannabis test
- ECG (if your ECG has changed during the study)
- Urine collection for urinalysis (if your test results have changed significantly during the study)
- Urine pregnancy test (for females)

- Collect urine in the morning and bring it to the clinic visit

If possible, some of the above procedures may be done remotely, through a Zoom call, before or after safety follow up visit.

Additional clinic visits may be necessary if you have abnormal lab results.

Regarding future CBD/marijuana use after you finish this study:

Cannabis (marijuana) is composed of many cannabinoid compounds and other substances, including Cannabidiol (CBD) and Tetrahydrocannabinol (THC). THC is the substance in cannabis that produces psychoactive effects. CBD limits THC's psychoactive effects. There is more THC and less CBD in street marijuana than in the drug you took for this study. Using marijuana is risky because the high

THC and low CBD may worsen current symptoms, such as cognitive, psychiatric and motor problems, including falling.

There are many forms of CBD being marketed. Using marijuana should be under the supervision of your physician, with monitoring the symptoms of PD and other disease, as well as the interactions of marijuana and other drugs you take.

Sleep Study Portion

You will also be asked to use a sleep monitoring device to monitor 2 nights of sleep. For this part of the study, you will also need to come to the clinic for 2 additional visits prior to using the sleep monitor to have the device set up and to receive instructions. The following will be done:

3-14 days before the Baseline Visit
You will come to clinic to have the sleep monitoring equipment set up and be instructed how to use it during the night at home. You will need to complete a sleep diary and a sleep questionnaires in the morning when you finish the sleep test. You will need to bring the equipment, sleep diary and the questionnaire to the clinic before or at baseline visit to have the data collected and reviewed.

Between your 7th night on the maximum dose and the 3rd night prior to the 2.5 mg/kg/day Dose Assessment Visit
You will come to clinic to have the sleep monitoring equipment set up and be instructed how to use it during the night at home. You will need to complete a sleep diary and a sleep questionnaires in the morning when you finish the sleep test. You will need to bring the equipment, sleep diary and the questionnaire to the clinic before or at the 2.5 mg/kg/day Dose Assessment Visit to have the data collected and reviewed.

Optional Consent for Data and Specimen Banking for Future Research

Dr. Leehey would like to keep some of the data and blood that is taken during the study but is not used for other tests. If you agree, the samples and data will be kept and may be used in future research to learn more about Parkinson's disease. The research that is done with your samples and data is not designed to specifically help you. It might help people who have PD and other diseases in the future. Reports about research done with your samples and data will not be given to you or your doctor. These reports will not be put in your health records. The research using your samples and data will not affect your care.

The choice to let Dr. Leehey keep the samples and data for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your samples and data can be kept for research, you can change your mind at any time and contact your study doctor to let him or her know that you do not want your samples and data to be used any longer, and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until Dr. Leehey decides to destroy them.

When your samples and data are given to other researchers in the future, Dr. Leehey will not give them your name, address, phone number or any other information that will let the researchers know who you are. One group that will potentially receive your de-identified data would be the CDPHE Marijuana Grantee Consortium.

Sometimes samples and data are used for genetic research (about diseases that are passed on in families). Even if your data and samples are used for this kind of research, the results will not be told to you and will not be put in your health records. Your data and samples will only be used for research and will not be sold. The research done with your data and samples may help to develop new products in the future, but there is no plan for you to be paid.

The possible benefits of research from your data and samples include learning more about what causes PD and other diseases, how to prevent them and how to treat them. The greatest risk to you is the release of your private information. Dr. Leehey will protect your records so that your name, address and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any sample or data collection and storage by Dr. Leehey.

Please read the sentence below and think about your choice. After reading the sentence, circle “yes” or “no.” If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and future use of your samples, you may still take part in the study.

I give my permission for my blood and data to be stored in a central tissue and data bank at University of Colorado Denver for future use by the study investigators:

☐ Yes ☐ No _____Initials

Optional Consent for Sharing Data with Primary Care Provider

It is important that your primary care provider is aware of your participation in the study. We would like your permission to share your study data and lab results with your primary care physician so they are fully informed about your care. If you agree, we will send a letter to them after each study visit updating them on your participation

I give my permission for you to share my study data and information about my participation with my PCP:

☐ Yes ☐ No _____Initials

If you agree, please provide the name, telephone number, and address of your primary care physician (if you do not have it right now, you can provide this to us at a later time):

_____

_____

_____

What are the possible discomforts or risks?

Risks of Study Drug

As with any drug, side effects are possible. You will need to report any unusual symptoms to your Study Doctor immediately. Possible side effects, which usually go away with time, include the following:
Most common (>20%): sleepiness, fatigue, decreased appetite, dizziness, and diarrhea.
Common (6-20%): increased appetite, increased weight, lethargy, acid stomach, urgency to have a bowel movement, burping, frequent bowel movements, vomiting, disorder of sense of taste, frequent urination, irritability, headache and skin rash.
Less common (5% or less): seizure/convulsion, decreased weight, trouble walking, increased serum concentrations of anti-seizure drugs, and elevated liver enzyme tests.

The study drug may interact negatively with a substance found in grapefruit. Therefore, **you should not eat grapefruit or drink grapefruit juice for 7 days prior to the first dose of study drug, or throughout your participation in the study.**

The study drug may interact with acetaminophen to produce increased acetaminophen levels in your body. Therefore, **you should not take more than 1000 mg of acetaminophen (such as Tylenol) per day while you are taking study drug.**

The study drug may interact with other drugs and supplements as well. You should notify the study doctor of all drugs and supplements that you are taking now and throughout the study.

The study drug should always keep in the container it is provided in.
Keep the study drug away from children and anyone that shouldn't use it. The study drug is to only be taken by you.
If you require medical care outside of the study while participating in this study, please show the other medical personnel this information.

Driving

Whether or not the study drug affects driving ability is not known. **You should not drive or operate heavy machinery while taking study drug. You must have a driver or available transportation to drive you to and from clinic and for any other transportation needs while you are taking study drug.**

Risk of Having Blood Taken

In this study we will need to get about 1-2 tablespoon of blood from you at each visit. We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube. You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise where the needle went under the skin.

Risk of Questionnaires

Some of the questions may seem personal and may make you feel uncomfortable. If you have any questions or concerns while completing these questionnaires, please talk to your study doctor.

Other

The study drug is mostly CBD, which has a different effect in the body than marijuana. Studies suggest that CBD does not cause the "high" that people get from marijuana. Persons should not drive when on marijuana because of the "high". The study drug may cause side effects such as dizziness, sleepiness or fatigue which may impair judgment and performance of skilled tasks.

The study drug has a tiny amount (<2%) of the part of marijuana that causes the "high" in it. Therefore, if you had blood testing for marijuana it could come back positive. We will provide you with a card explaining this to carry with you.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

It is possible that you may experience fatigue from long study visits. We will take breaks as often as necessary.

If you become pregnant, the particular treatment involved in the study may involve risks to the embryo or fetus which are currently unclear. Therefore men and women of child bearing potential should take

reliable contraceptive precautions for the duration of the study and for 3 months after finishing the study.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the study drug as a treatment in patients with PD. However, there is no guarantee that your health will improve if you join this study. Also, there could be risks to being in this study. If there are risks, these are described in the section describing the discomforts or risks.

Are there alternative treatments?

There may be other ways of treating your PD. These other ways include other medications and surgical therapy. You could also choose to get no treatment at all.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is being sponsored by the Colorado Department of Public Health and Environment.

The study drug is being provided by National Institute on Drug Abuse (NIDA).

Will I be paid for being in the study?

You will be paid $*25.00* for each in-clinic visit in this study. On these days you will also be offered a lunch voucher for yourself and one person that comes with you to the visit, if you bring someone. This will add up to a total of $*175.00* if you complete all of the visits. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study is taxable income.

If necessary, limited funds for use of transportation will be provided during the time you are taking study drug.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Leehey immediately at 303-724-8984 or contact Ying Liu at 720-921-4815 outside of regular work hours.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Maureen Leehey. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Leehey at 303-724-8984. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Leehey with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

You may also contact a Subject Advocate at the Clinical and Translational Research Center (CTRC). The number there is 720-848-6662.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include

- University of Colorado Denver
- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Maureen Leehey, MD
12631 E. 17th Ave, mailstop B185
Aurora CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- People at the Colorado Department of Public Health and Environment

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Psychological and mental health tests
- Alcoholism, Alcohol or Drug abuse

What happens to Data, Blood, and Specimens that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data, blood, and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, blood or specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, blood or specimens collected from you.
- If data, blood, or specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

A Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your privacy. This Certificate means that the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. But, if you request disclosure, we can release the information.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project if they find out that you have intent to harm yourself or others. This also applies to any information about past or present child abuse.

You should also take measures to ensure your own privacy.

HIPAA Authorization for Optional Additional Study Procedures
In this form, you were given the option to agree to have your samples stored for future research. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

Some of these optional procedures may involve genetic testing or the use of your genetic information. Your genetic information will not be released to others

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Signature Line For LAR, if applicable **N/A (LAR not required)**

_____ Date_____
Legally Authorized Representative

Print Name: _____

Signature Line for witness; required for consent of non-reading subjects **N/A (witness not required)**

Witness Signature:_____ Date_____

Witness Print Name:_____

Witness of Signature
Witness of consent process