|  |  |
| --- | --- |
| Extension | **Informed Consent Document** |

**TITLE OF RESEARCH:** Protocol for the Evaluation of the Safety and Efficacy of Trimycin vs. Hydrochlorothiazide in the Treatment of Essential Hypertension

**IRB PROTOCOL: 1234567**

**INVESTIGATOR:** Dr. Jane Doe

**SPONSOR:** Wise Drug Company, Inc.

Explanation of Procedures

We are asking you to take part in a research study. This research study will test how well a new drug lowers blood pressure. The new drug, Trimycin, is investigational and not yet approved by the U.S. Food and Drug Administration (FDA). Wise Drug Company, the company that makes Trimycin, is paying for the study. People who enter into the study will take either the new drug, Trimycin, or Hydrochlorothiazide (water pill). Hydrochlorothiazide is the FDA approved drug that most people take now to lower blood pressure. Trimycin is approved in Europe, but has not been approved in the United States. More than 200 people in other research studies in the United States have safely used Trimycin. This is a Phase III study. A Phase III study is a research study that looks at a large number of patients receiving a common or routine treatment. This study will enroll 200 participants nationwide, and 20 of them will come from University of Mythos.

If you enter the study, all your current blood pressure medicines will be stopped for 1 month. During this time, you will be given pills called placebos. A placebo does not have any active medicine, so it should not have any effect on your blood pressure. However, this placebo might cause your blood pressure to lower. The study staff will need to watch your blood pressure closely while you are not on any medicine for your blood pressure. Your blood pressure will be watched to make sure it does not rise so high that you need immediate treatment. You will need to come for office visits three times during the first week. You will need to come for office visits two times per week during Weeks 2, 3, and 4. If your blood pressure is in the range required after Week 4, you will be entered into the study. If your blood pressure is not in the range required after Week 4, you will not be entered into the study and will receive standard care for your blood pressure. If you are entered and complete the entire study, you will be in the study for 6 months.

If you qualify for the study, you will be randomly picked (like the flip of a coin) by a computer to receive either Trimycin or Hydrochlorothiazide. You will take the medicine once a day by mouth. This will be a double-blind study. This means neither you nor your doctors will know which medicine you are taking. If medically necessary, the doctor can find out which drug you are taking.

These tests will be made during the study: lab blood tests, urine tests, weight measures, resting electrocardiogram, heart rate, and blood pressure. (An electrocardiogram measures the electrical activity of the heart.) You will be asked to come back to the clinic for 20 weekly visits. At each visit you will be asked if you have had any bad reactions and how you are feeling on the drug.

Risks and Discomforts

You may have some side effects from taking these drugs. The side effects of Trimycin are headaches, feeling drowsy, and feeling tired. About forty percent (40%) of people who take Trimycin have reported feeling drowsy and tired. About twenty percent (20%) of people who take Trimycin have headaches. Hydrochlorothiazide can cause the following side effects: low blood potassium; a rise in blood uric acid and blood sugar; and a lowering of red and white blood cells. About eighty percent (80%) of people who take Hydrochlorothiazide have these problems. There may also be risks that are unknown at this time. You will be given more information if other risks are found.

Information for Women of Childbearing Potential or
Men Capable of Fathering a Child

We do not know if the study drug will affect mother’s milk or an unborn fetus. Therefore, breast-feeding and pregnant women are not allowed to take part in the study. If you are pregnant or become pregnant, there may be risks to the embryo or fetus that are unknown at this time. Women who can become pregnant must take a pregnancy test before the start of the study.

You should not father a child while on this study as the treatment may indirectly affect an unborn child. If you are sexually active and are at risk of causing a pregnancy, you and your female partner(s) must use a method to avoid pregnancy that works well or you must not have sex.

Unless you cannot have children because of surgery or other medical reasons, you must have been using an effective form of birth control before you start the study. You must also agree to continue to use an effective form of birth control for 6 months after taking the study drug. Effective birth control includes birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, or avoiding sexual activity that could cause you to become pregnant.

Benefits

You may not benefit directly from taking part in this study. However, this study may help us better understand how to treat high blood pressure in the future.

Alternatives

There are many other drugs that are used to treat high blood pressure. Some examples of these drugs are Betasan, Enapror, and Ditserin. The investigator or research staff will discuss these other drugs with you.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the University of Mythos Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of Wise Drug and the Office for Human Research Protections (OHRP). The results of the treatment may be published for scientific purposes. These results could include your lab tests and X-rays. However, your identity will not be given out.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

If any part of this study takes place at University of Mythos, this consent document will be placed in your file at that facility. The document will become part of your medical record chart.

Monitors, auditors, the Institutional Review Board for Human Use, and regulatory authorities will be granted direct access to your original medical records for verification of trial procedures and/or data without violating confidentiality.

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of University of Mythos Health System affiliated entities so that claims may be appropriately submitted to the study sponsor or to your insurance company for clinical services and procedures provided to you during the course of this study.

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.

Refusal or Withdrawal without Penalty

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons so you can be taken off the study drug and referred for follow-up care.

You may be removed from the study without your consent if the sponsor ends the study, if the study drug is approved by the FDA, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a University of Mythos student or employee, taking part in this research is not a part of your University of Mythos class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at University of Mythos. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

If you are in Medicare Advantage (Medicare managed care plan), you should contact someone at your plan before you start a clinical trial. They can provide more information about additional costs you could incur from participating in clinical trials.

There will be no cost to you for taking part in this study. All drugs, exams, and medical care related to this study will be provided to you at no cost during the 6-month study period. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Payment for Participation in Research

You are responsible for paying any state, federal, Social Security or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your check.

You will be paid $10 for each study visit, including the placebo phase of the study. If you quit the study, you will be paid $10 for each study visit made to the clinic. Payments will be made after 3 months and 6 months if you complete the entire study. If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. If you complete the entire study, you will receive a total of $290.

Payment for Research-Related Injuries

University of Mythos has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by your doctor or the study staff if new information becomes available and might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research- related injury including available treatments, please contact Dr. Jane Doe. She will be glad to answer any of your questions. Dr. Doe’s number is xxx-555-3810. Dr. Doe may also be reached after hours by paging her at xxx-555-3411 (beeper 9999).

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Ms. Sheila Moore. Ms. Moore is the Director of the Office of the Institutional Review Board for Human Use (OIRB) at the University of Mythos. Ms. Moore may be reached at (xxx) 555-3789 or 1-800-555-8816. If calling the toll-free number, press the option for “all other calls” or for an operator/attendant and ask for extension 4-3789. Regular hours for the Office of the IRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Genome-Wide Association Studies (GWAS)

The DNA that composes your genes will be analyzed and that data, which is referred to as your genotype or complete genetic makeup, will be compared to your phenotype, which consists of your observable traits, characteristics, and diseases. Your genotype and phenotype data will be shared for research purposes through the National Institutes of Health (NIH) Genome-Wide Association Studies (GWAS) data repository. The aim of this research is to discover genetic factors that contribute to the development, progression, or therapy for a particular disease or trait.

Storage of Specimens for Future Use

Please initial your choice below:

\_\_\_ I agree to allow my samples to be kept and used for future research on hypertension.

\_\_\_ I do not agree to allow my samples to be kept and used for future research.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.

Signature of Participant Date

Signature of Principal Investigator Date

Signature of Witness Date

University of Mythos at Atlantis

**AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION**

**FOR RESEARCH**

**What is the purpose of this form?** You are being asked to sign this form so that University of Mythos may use and release your health information for research**.** Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

|  |  |
| --- | --- |
| Participant Name:  | University of Mythos IRB Protocol Number: 123456 |
| Research Protocol: Protocol for the Evaluation of the Safety and Efficacy of Trimycin vs. Hydrochlorothiazide in the Treatment of Essential Hypertension | Principal Investigator: Dr. Jane Doe |
| Sponsor: Wise Drug Company |

**What health information do the researchers want to use?** All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

**Why do the researchers want my health information?** The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

**Who will disclose, use and/or receive my health information?** The physicians, nurses and staff working on the research protocol (whether at University of Mythos or elsewhere); other operating units of University of Mythos, Atlantis County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

**How will my health information be protected once it is given to others?** Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

**How long will this Authorization last?** Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

**Can I cancel the Authorization?** You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

**Can I see my health information?** You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: Date:

**or** participant's legally authorized representative: Date:

Printed Name of participant’s representative:

Relationship to the participant:

*Fictional informed consent form adapted from* www.uab.edu/irb/forms/sample-consent-form.doc