LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER in NEW ORLEANS
Informed Consent Form-Main

1. Study Title: CITN-09: Phase II Study of MK-3475 in Patients with Advanced Merkel Cell Carcinoma (MCC)

2. Performance Sites: University Medical Center, 2000 Canal Street, New Orleans, LA 70112

3. Investigators:

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4. Purpose of Study:

INTRODUCTION

We are asking you if you would like to join this research study. Research is not the same as treatment or medical care. A research study answers scientific questions.

This consent form will help you decide whether joining the study is right for you. Please read this form carefully. We can read it with you if you want. Ask questions about anything that is not clear. Also, you can talk to people whom you respect to help you decide about joining the study. If you agree to join, you will sign or mark this consent form. We will offer you a copy to keep.

WHY IS THIS STUDY BEING DONE?

The main purpose of this study is to find out how people with advanced Merkel cell cancer respond to study drug called MK-3475. MK-3475 is an experimental medication that is being used to stimulate your immune system to destroy cancer cells. We will refer to it from here on as "the study medication." It works differently than traditional chemotherapy agents. We hope that the study medication will increase the number and function of certain T-cells in your immune system. T-cells can identify and destroy cancer cells.

Another purpose of this study is for researchers to learn if blood or tumor tests can be used to identify patients who are likely to respond to treatment with the study medication.

The study drug, MK-3475, is not FDA approved for treating Merkel cell cancer.

5. Description of the Study:

WHAT IS THE USUAL APPROACH TO TREATING MERKEL CELL CANCER?

You are being asked to take part in this study because you have advanced Merkel cell cancer. People with this disease affecting limited areas of their body (local disease) are usually treated first with therapies such as surgery and radiation therapy. You may qualify for this study if you

have local disease that did not respond to surgery and radiation therapy. For patients with more widespread disease (present in more than one location of the body), the usual treatment is chemotherapy, which often causes tumors to shrink initially, but rarely controls tumors for longer than 6 to 9 months. Chemotherapy agents used in treatment of Merkel cell cancer include etoposide and carboplatin, which are given as an injection into a vein, and pazopanib (an oral medication). If you have widespread disease, that has not been treated with chemotherapy, you may also qualify for this study.

If you decide to participate in this study, you will not be able to receive chemotherapy at the same time. If chemotherapy treatment is needed for your disease, it must be delayed until you are off the study.

This study is being conducted by the Cancer Immunotherapy Trials Network (CITN), sponsored by the National Cancer Institute. The CITN administrative coordinating center is located at the Fred Hutchinson Cancer Research Center (FHCRC) and works with researchers from several cancer centers and universities across the country.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
Up to 50 people will take part in this study nationally. About 5 people may take part at LSUHSC-NO and its affiliates.

WHO WILL GET THE STUDY MEDICATION?
Everyone who participates in this study will receive the study medication, which is given as a 30-minute intravenous infusion in an outpatient clinic.

HOW LONG WILL I BE IN THIS STUDY?
You will get the study medication every 3 weeks or 21 days (this is also called a cycle) as long as you continue to benefit from the treatment, for up to 2 years. If your cancer spreads, causing more symptoms, or if you do not respond well to the medication, we will stop giving it to you. If your cancer spreads, but you do not have other concerning symptoms, your doctor may talk to you about continuing the study medication. A small number of patients with melanoma, another type of skin cancer, have had late responses to this medication, so it may be possible that some patients with Merkel cell cancer may also have late responses. If you respond well to the medication and your disease goes away you may be able to stop receiving the study medication after about 6 months of treatment. If your cancer then returns, you may be able to be treated again with the study medication.

WHAT TESTS AND PROCEDURES WILL I HAVE IF I JOIN THIS STUDY?
Most of the exams, tests, and procedures you will have during this study are part of the usual approach for your cancer. However, there are some additional exams, tests, and procedures that you will have if you join this study.

In order to find out if you are eligible to be in the study, we will perform some procedures. We will:

- Give you a physical examination.
- Record your vital signs including your height and weight

- Give you a pulmonary function test if you have a history of smoking or breathing problems. This test will see how well your lungs work.
- Give you a test called an EKG to learn about your heart.
- Ask you questions about your health and the medications that you take.
- Draw some blood as described in the blood collection table. This sample will be used to review how well your kidneys are functioning and test for pregnancy in woman of child-bearing age.
- Collect a urine sample.
- Give you CT scans for tumor measurements.
- Ask your permission to obtain a sample of your tumor tissue.
    - If you have already had surgery to remove Merkel cell cancer, it is likely that your doctor has sent that tissue to a pathologist to establish the diagnosis. The pathologist may release some leftover tissue to us for this research study.
    - If there is not tissue available from an earlier biopsy, we would take a biopsy of one of your tumors for testing. The doctor will remove a small piece of your tumor using a needle, a circular blade called a punch, or a small scalpel.

Neither you nor your health care plan/insurance carrier will be billed for the exams or the sample collections that will be used for this study if they are not part of your usual care.

If the exams, tests, and procedures show that you are eligible to be in this study, and you choose to join, you will be asked to return to the clinic every 3 weeks to complete your study visits. The number of visits you will be asked to complete will depend upon how well you respond to the study medication. During these visits, you will either receive study medication or study medication and specific tests/procedures. These exams, tests, or procedures may not be part of the usual approach for your type of cancer. Please ask your study doctor what exams, tests, and procedures are the usual approach for your cancer.

During the study visits, we will do the following:

- Give you a dose of the study medication every 3 weeks.
- Take blood samples as described in the collection table below.
- Take a CT scan for tumor measurements around the time of the fifth dose of study medication, and then around every third dose (every 9 weeks). After one year, you would have a CT only every fourth dose (every12 weeks).
- Ask you questions at each visit about your health and any symptoms you may be having. We will also ask about your medications.
- Give you up to three EKG tests (after the 1^{st} and 8^{th} dose and when treatment is stopped).
- Give you a physical examination every 3 weeks.
- Collect a urine sample every 6^{th} cycle (every 18 weeks).

Each visit that includes the infusion of the study medication will be approximately 2-3 hours long.

Each visit that also includes a CT-Scan, EKG or laboratory procedures will be approximately 4 hours long.

If you agree, we will collect extra blood samples and an extra biopsy:
If your physical exams or CT scans show that your tumor is getting larger, the study doctor will discuss with you whether to stop or continue the study medication. The doctor will also ask you if you will agree to a biopsy of your tumor. This biopsy can be requested any time once you have begun the study medication.

The study doctor may also ask you if you will agree to a biopsy of your tumor if your physical exams or CT scans show that your tumor is getting smaller or is not changing in size.

If you agree to the optional biopsy, the doctor will remove a small piece of your tumor using a needle, a circular blade called a punch, or a small scalpel. The tests done on this optional biopsy would only be used for research and not to guide your medical care.

If you agree, additional blood samples will be collected during your scheduled blood draws for storage in a biobank. In addition, we would also like your permission to store any leftover biopsy samples or blood samples that we do not use during the study in the biobank. Storing samples for future studies is called "biobanking."

You will be provided a separate Informed Consent Form for these optional samples. We will ask you if you will allow us to collect and store these optional and leftover samples. You can decide not to give these extra samples and still be in the study. You can decide to provide some of the samples and not others. If you agree to provide these samples, you can change your mind at any time during the study.

Blood Collection:
During the pre-study phase of the trial and throughout the treatment phase of the trial, we will draw differing amounts of blood at each visit. *The blood will be collected by inserting a needle in your vein or when possible using an existing port in your vein or at the same time as other blood collection procedures.* Neither you nor your health care plan/insurance carrier will be billed for the collection of the *blood* that will be used for research purposes.

The blood will be used for three distinct purposes including:

1) Safety labs: These are tests that help us monitor any good or bad effects on your body that the study medication might have. We will review how well your organs are functioning (chemistry panel), your blood count (CBC with differential), and test for pregnancy in woman of childbearing age. These safety labs are similar to the labs we would monitor for patients receiving other types of cancer therapy.
2) Research labs: These samples are required in order for you to take part in this study because the research on your blood is an important part of the study. *This blood will help us understand how your body, especially your immune system, is responding to the study medication. The tests done for research purposes are different from the tests done for safety monitoring.*

3) Biobanking: *These blood draws are optional. This blood will be stored for studies that may be conducted in the future and is discussed in detail in the separate OPTIONAL TISSUE AND BLOOD SAMPLE COLLECTION and BIOBANKING informed consent form.*

The blood collection visits in the table below are listed by Cycle. A Cycle is 3 weeks. The volumes of blood that we will draw at each visit for the purposes mentioned above include:

Cycle	**Safety Labs**	**Research Labs**
Pre-study	26 ml (about 5 teaspoons) if female, and 20 ml (4 teaspoons) if male	
Cycle 1		160 ml (2/3 cup)
Cycle 2	7 ml (about 1½ teaspoons)	145 ml (1/2 cup plus 5 teaspoons)
Cycle 3	7 ml (about 1½ teaspoons)	
Cycle 4	7 ml (about 1½ teaspoons)	
Cycle 5	7 ml (about 1½ teaspoons)	150 ml (1/2 cup plus 2 tablespoons)
Cycle 6	17 ml (about 3½ teaspoons)	
Cycle 7	7 ml (about 1½ teaspoons)	
Cycle 8	7 ml (about 1½ teaspoons)	135 ml (1/2 cup plus 1 tablespoon)
Cycle 9	7 ml (about 1½ teaspoons)	
Cycle 10	7 ml (about 1½ teaspoons)	
Cycle 11	7 ml (about 1½ teaspoons)	135 ml (1/2 cup plus 1 tablespoon)
Cycle 12	17 ml (about 3 ½ teaspoons)	
Cycle 13	7 ml (about 1½ teaspoons)	
Cycle 14	7 ml (about 1½ teaspoons)	135 ml (1/2 cup plus 1 tablespoon
Cycle 15	7 ml (about 1½ teaspoons)	
Cycle 16	7 ml (about 1½ teaspoons)	
Cycle 17	7 ml (about 1½ teaspoons)	135 ml (1/2 cup plus 1 tablespoon)
Cycle 18	7 ml (about 1½ teaspoons)	
Cycle 19	7 ml (about 1½ teaspoons)	
Cycle 20	7 ml (about 1½ teaspoons)	
Cycle 21	7 ml (about 1½ teaspoons)	
Cycle 22	7 ml (about 1½ teaspoons)	
Cycle 23	7 ml (about 1½ teaspoons)	
Cycle 24	17 ml (about 3 ½ teaspoons)	
Cycle 25	7 ml (about 1½ teaspoons)	
Cycle 26	7 ml (about 1½ teaspoons)	
Cycle 27	7 ml (about 1½ teaspoons)	
Cycle 28	7 ml (about 1½ teaspoons)	
Cycle 29	7 ml (about 1½ teaspoons)	
Cycle 30	17 ml (about 3 ½ teaspoons)	
Cycle 31	7 ml (about 1½ teaspoons)	
Cycle 32	7 ml (about 1½ teaspoons)	
Cycle 33	7 ml (about 1½ teaspoons)	
Cycle 34	7 ml (about 1½ teaspoons)	

Cycle	Safety Labs	Research Labs
Cycle 35	7 ml (about 1½ teaspoons)	
End of Study	13 ml (about 2 ½ teaspoons) if female, and 7 ml (about 1 ½ teaspoons) if male.	150 ml (1/2 cup plus 2 tablespoons)
Post-Treatment Follow-Up, at 30 days	17 ml (about 3 ½ teaspoons)	

If you have low blood counts (anemia), we will draw less blood than is stated in the table.

WHERE CAN I GET MORE INFORMATION?
You may visit the NCI Web site at http://cancer.gov/ for more information about other studies you may be interested in joining or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

The National Clinical Trials number for this study is NCT 02267603.

6. Benefits to Subjects:
This study may or may not help you because researchers do not know how the study medication will compare to the usual treatment approach. This study may help researchers learn things that may help people in the future.

If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

7. Risks to Subject:
WHAT POSSIBLE RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?
If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual.
- You may be asked sensitive or private questions that you normally do not discuss. You may also refuse to answer any question that makes you uncomfortable.
- You may feel embarrassed during the physical exam. You may request that the physical exam be done by a clinician of the same gender.
- There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. There are laws against misuse of genetic information, but they may not give full protection. We will tell you more about how we will protect your personal information later in the consent.

- There can also be a risk in finding out new genetic information about you. New health information about inherited traits that might affect you or your blood relatives could be found during a study.

The study medication may affect how different parts of your body work, such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health. If the study medication causes changes in how your organs work, it is possible that it would be unsafe to administer chemotherapy to you in the future.

There is also a risk that you could have side effects from the study medication/study approach.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects of the study medication that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

PLEASE NOTE THE FOLLOWING IN REVIEWING THESE RISKS:

MK-3475 is an agent involved in the inhibition of “immune checkpoints,” and may result in severe and possibly fatal immune-mediated side effects probably due to activation and growth of immune cells (T-cells). Immune-mediated side effects have been reported in patients receiving MK-3475. In clinical trials, most immune-mediated side effects were reversible and managed by stopping MK-3475 temporarily, administration of corticosteroids and supportive care.

COMMON, SOME MAY BE SERIOUS In 100 people receiving MK-3475, more than 20 and up to 100 may have:
• Tiredness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving MK-3475, from 4 to 20 may have:
• Anemia which may require blood transfusion • Pain • Pain and swelling of thyroid • Diarrhea, nausea • Sores in the mouth which may cause difficulty swallowing • Chills, fever • Swelling of the body which may cause shortness of breath • Infection • Loss of appetite • Damage to the bone which may loss of motion • Fluid in the joints • Joint stiffness • Blisters on the skin, itching, acne, rash, skin changes, hives • Swelling and redness of the skin • The body's reaction to the drug can occur during treatment or weeks to months later: multiple organs may be involved but primarily bowels, liver, skin, nerves and glands that make hormones; symptoms may include diarrhea, rash and numbness/tingling of hands and feet

RARE, AND SERIOUS In 100 people receiving MK-3475, 3 or fewer may have:
• Heart failure which may cause shortness of breath, swelling of ankles, cough or tiredness • Swelling and redness of the eye • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Reaction during or following a drug infusion which may cause fever, chills, rash • Weakness and paralysis • Muscle weakness • Feeling of "pins and needles" in arms and legs • Kidney damage which may require dialysis • Severe skin rash with blisters and can involve inside of mouth and other parts of the body

There have been additional side effects seen in patients who have participated in trials using

MK-3475. Some of these have been serious. We do not know for certain whether these side effects were caused by MK-3475. These additional side effects have included:

- Damage to the bone marrow (irreversible) which may cause bleeding, may require blood transfusions
- Fluid around heart which can stop the heart from beating
- Constipation
- Cough
- Headache
- Shortness of breath
- Vomiting
- Weight loss

Risks of CT scans:
Any scans done while you are on the study will be ordered by your physician as routine or standard-of-care scans. The CT scans that you will receive in this study will expose you to low amounts of radiation. Every day, people are naturally exposed to low levels of radiation that come from the sun and the environment. No one knows for sure whether exposure to low amounts of radiation is harmful for your body. However, scientists believe that being exposed to too much radiation can cause harmful side effects, including causing a new cancer.

Reproductive risks:
You should not become pregnant, breastfeed, or father a baby while in this study because the study medication may affect a developing baby. In addition, you should not become pregnant, breastfeed, or father a baby for 120 days after the last dose of study medication.

It is important that you use 2 methods of birth control from the time you sign this consent form until 4 months after you stop receiving the study medication. This includes both men and women who participate in the trial. We will talk with you about your birth control choices. Some methods might not be approved for use in this study.

If you are a female and become pregnant, we will stop giving you the study medication. We will follow the outcome of your pregnancy. If you are a man and your female partner becomes pregnant, please tell us. We will ask permission to follow the outcome of the pregnancy.

Risks of blood draws:
The most common risks related to drawing blood from your arm are brief pain and possibly a bruise. There is a very small chance that you could get an infection where we take the blood. You might also feel lightheaded or even faint. You could develop anemia or need a blood transfusion. Please tell the study staff if you are in another study or have a medical procedure where blood is drawn.

Risks of EKG:
When the electrodes are removed from your chest after having the EKG, it may cause discomfort. The feeling is similar to removing a bandage.

Risks of biopsies:
Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain at the biopsy site, bruising, swelling, and scarring. Rarely, an infection can occur.

8. Alternatives to Participation in the Study:
If you decide not to take part in this study, you have other choices. For example:

- You may choose to have the usual approach described above.
- You may choose to take part in a different study, if one is available.
- You could decide not to be treated.
- You may choose to get comfort care. This type of care helps reduce pain, tiredness, appetite problems, and other problems caused by cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Each of these choices has risks and benefits. You should talk to your doctor about them. The alternative is not to participate.

9. Subject Removal:
The study doctor may take you out of the study if:

- Your health changes and the study is no longer in your best interest,
- New information becomes available,
- You do not follow the study rules, or
- The study is stopped by the sponsor, IRB, or FDA.

10. Subject's Right to Refuse to Participate or Withdraw:
Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You may refuse to participate or withdraw from the study at any time without jeopardizing, in any way, your medical treatment at this institution in the present or future. Information already collected about you and sent to the sponsor will still be used. Tell the researcher if you are thinking about withdrawing from the study so that you may do so safely. If you decide not to continue participation in the study you should seek medical advice for alternatives. Should significant new findings take place during the course of the research that may relate to your willingness to continue participation, that information will be provided to you.

11. Subject's Right to Privacy:
Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimens, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose

information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. 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 Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

HOW IS MY GENETIC INFORMATION PROTECTED?
A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect your genetic information. GINA restricts access to your genetic information so that it cannot be used for health insurance coverage decisions. GINA won't allow health insurance companies or group health plans to:

- Ask for your genetic information you have provided in research studies; or
- Use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not help or protect you against genetic discrimination by companies that sell life, disability, or long-term care insurance.

Louisiana law prohibits discrimination in employment or insurability based on your genetic information. Your genetic information is considered your property and no insurer or employer may obtain genetic information or a DNA sample without first obtaining your written consent. (LA Statute RS22:1023 and RS23:368).

12. <u>Release of Information</u>:
These organizations may inspect and/or copy your study-related medical records for quality assurance and data analysis and these organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The Cancer Immunotherapy Trials Network (CITN), and the people who work for it;
- The Fred Hutchinson Cancer Research Center (FHCRC) and the people who work for it;
- The study sponsor, The National Cancer Institute, and any drug company, Merck, supporting the study;
- The LSUHSC-NO Institutional Review Board (IRB), which is a group of people who review the research with the goal of protecting the people who take part in the study;
- Safety monitoring committees;

- The U.S. Food and Drug Administration (FDA), the U.S. National Cancer Institute (NCI), the U.S. Office for Human Research Protections (OHRP), and other government agencies that oversee research.
- The doctors listed on page 1 of this consent form and their staff.

While every effort will be made to maintain your privacy, absolute confidentiality cannot be guaranteed. Records will be kept private to the extent allowed by law.

13. Financial Information:

The study medication will be supplied at no charge while you take part in this study. Although unlikely, it is possible that the *study medication* may not continue to be supplied free while you are on the study. If this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will continue to pay for the other costs of *treating* your cancer while in this study, including the cost of treating any side effects you experience from the study medication and procedures related to the administration of the study medication. Before you decide to join the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

The costs of all drugs, visits, procedures and study-related and unforeseen complications must be met by the subject. The treatments required are felt to be a part of good medical care and are for the most part covered by most insurance companies. The principal investigator will arrange for medical care for any emergency medical problem that you may experience as a direct result of your participation in this research. This will be provided on a fee-for-service basis. There are not funds available to pay for any disability that results or for damages such as lost wages, etc.

You will not be paid for your participation as reimbursement for your time and travel.

WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART IN THIS STUDY?

If you feel you have been injured or hurt as a result of taking part in the study, it is important that you tell the study doctor. You will get medical treatment if you are injured or hurt as a result of taking part in this study.

The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance coverage, you would be responsible for any costs. Even though you are in a study, you keep all of your legal rights to receive payment for injury caused by medical errors.

14. Signatures:

The study has been discussed with me and all my questions have been answered. Additional questions regarding the study should be directed to the investigators listed on page 1 of this consent form. If I have questions about subject's rights, or want to discuss problems, concerns or questions, or obtain information or offer input, I can contact the Chancellor of the LSU Health Sciences Center New Orleans at (504) 568-4801. I agree with the terms above, acknowledge I have been given a copy of the consent form, and agree to participate in this study. I have not waived any of my legal rights by signing this consent form.

_____ _____
Signature of Subject Date

_____
Printed Name of Subject

_____ _____
Consent Administered by Date

_____
Printed Name

The study subject has indicated to me that the subject is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to take part.

_____ _____
Signature of Reader Date

_____
Printed Name

_____ _____
Signature of Witness Date

_____
Printed Name