Document Coversheet

Study Title:

Enhancing Relapse Prevention with rTMS: Dose-Response Parameters for Smoking Cessation

Institution/Site:	Roswell Park Comprehensive Cancer Center
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ROSWELL PARK CANCER INSTITUTE

Title: Enhancing Relapse Prevention with rTMS: Dose-Response Parameters for Smoking Cessation

Principal Investigator:
Christine Sheffer, PhD
Roswell Park Comprehensive Cancer Center
Elm and Carlton Streets
Buffalo, NY 14263
(716) 845-1186

Roswell Park Study Number: I 65718

Consent Form Given to Patient Taking Part in an Investigational/Clinical Research Study

KEY INFORMATION ABOUT THIS RESEARCH STUDY

This is a clinical research study being done by the doctors at the Roswell Park Comprehensive Cancer Center. The sponsor of this study is the National Institutes of Health.

We are asking you to take part in this study because you are a healthy volunteer interested in testing the use of repetitive transcranial magnetic stimulation (rTMS) as a treatment for tobacco dependence and relapse prevention.

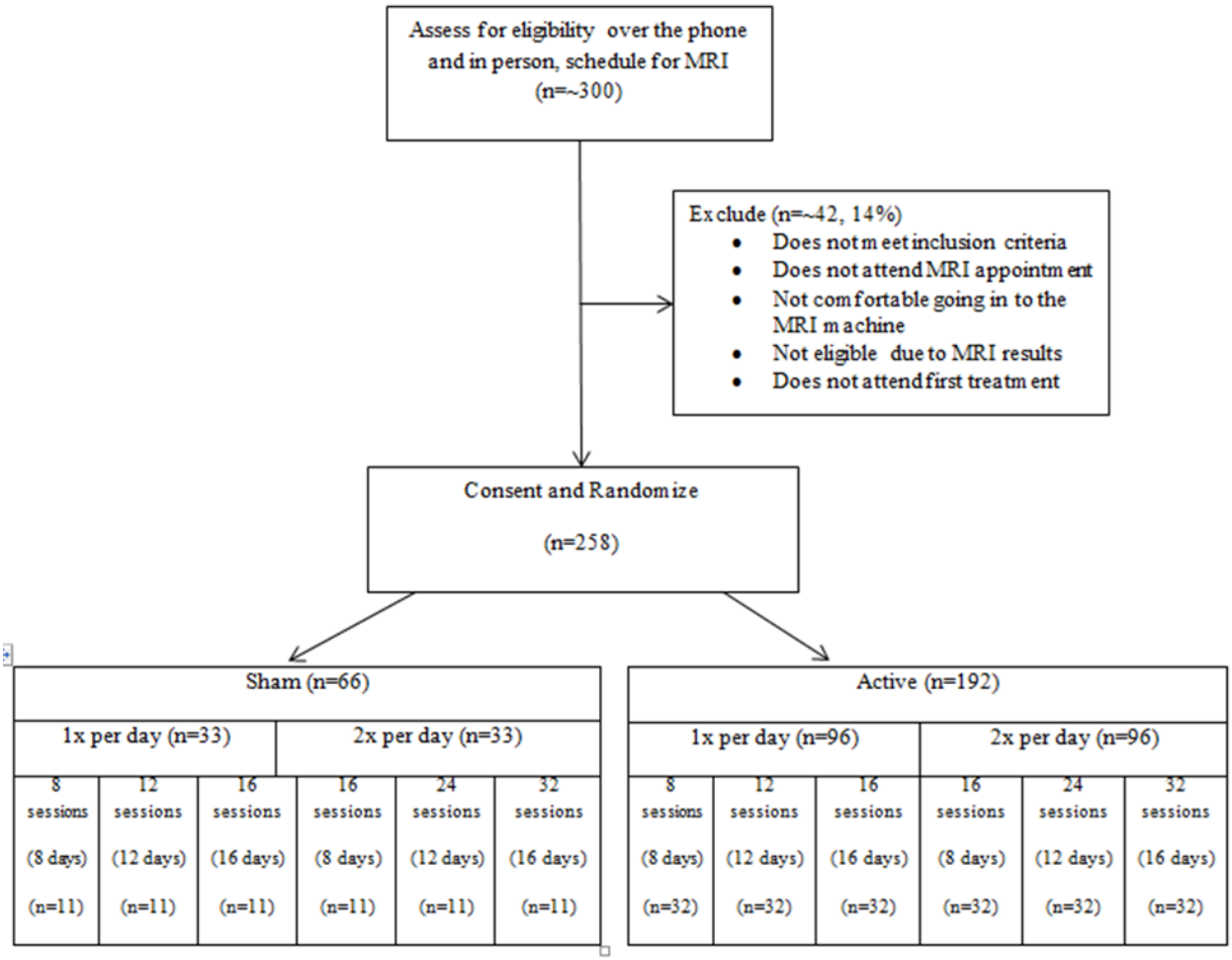
Clinical research studies include only those patients who choose to take part.

- Your participation is voluntary. You may decide not to participate in this research study.
- You do not have to participate in this study to receive treatment for your condition.
- If you do participate, you may withdraw from the research study at any time.
- Please take your time to make your decision. Discuss it with your family and with people who are important to you.

Study Purpose: The purpose of this study is to determine a dosing strategy for 20Hz rTMS that will produce the best long-term abstinence outcomes with the fewest undesirable side effects.

Study Duration and Number of Participants: It is expected this study will take about 5 years or will continue until the needed number of participants are enrolled. This study will include about 300 patients nationally.

Your participation in this study will be about 8 to 10 months. The image below shows different arms of the study and how different participants may be involved for different lengths of time.



Listed below are key research-related procedures that you will undergo during the study:

- Questionnaires completed on a computer at baseline
- A urine drug screening
- An MRI of the brain where a vitamin capsule will be placed on your forehead to show the stimulation spot
- Brief structured counseling for smoking cessation
- A 24-hour abstinence period where we ask you to refrain from smoking before your first rTMS stimulation session
- Expired carbon monoxide tests
- 8-16 days of active or sham rTMS stimulation, either once or twice per day
- Brief questionnaires completed on a computer at each stimulation session
- Questionnaires completed on a computer 4-, 8-, 12-, 18-, and 24-weeks after the quit day

Side Effects and Risks: While you take part in this study, you are at risk for side effects. The side effects may be mild, moderate, or severe. Many side effects go away shortly after the treatment stops.

The most common side effects of the MRI are:

- *Anxiety*: Some people might experience anxiety during the scanning process. MRI scans are performed in small enclosures that could cause anxiety. Participants will spend up to 30 minutes in this enclosure.
- *Incidental MRI findings*: A radiologist reads each MRI scan to ensure safe participation in the study and rule out brain abnormalities. MRI scans can reveal an undiagnosed brain abnormality that would exclude the participant from study but might also bring awareness of a previously unknown brain abnormality that might be quite serious (e.g., tumor, aneurism, etc.) and for which treatment is risky. Any findings from the MRI scan will be made known to you and we will provide a referral for follow-up with an appropriate medical specialist if abnormalities are discovered.

The possible risks associated with rTMS are:

- *Seizure*: There is a low risk of seizure associated with rTMS. Seizures associated with TMS have been reported more frequently in subjects with brain lesions (e.g., stroke). The stimulation parameters in this study are determined to be safe for use in human subjects. Using these guidelines, there has been little evidence of seizure during or after rTMS in normal subjects.

- *Effects on cognition*: There might be a risk for adverse cognitive effects after rTMS. Several studies show no adverse cognitive effects, some studies demonstrate improved performance on cognitive measures, but some studies show possible adverse effects in logical memory loss lasting up to one hour after high frequency rTMS.

- *Effects on mood*. There might be a risk for dysphoria after rTMS; however, high-frequency rTMS has been shown to improve mood and rTMS is an FDA-approved treatment for medication resistant depression as well.

- *Effects on Hearing*: Animals have shown permanent increases of the auditory threshold after single-pulse TMS and humans have shown transient increases. Foam earplugs were effective in avoiding changes in the auditory threshold in a safety study of TMS. Foam earplugs will be used in our investigation. With earplugs, there have been no reported effects on hearing using the rTMS parameters in this study.

- *Effects on Reproduction:* There is no evidence to suggest that rTMS alters reproductive capacity in men or women. As a precaution we screen participants for pregnancy and pregnant women are excluded.

- *Scalp Burns*: Rapid rate and high-stimulus intensity rTMS may cause the coil to heat, resulting in scalp burns. The Magstim coil that we use is cooled and incorporates a temperature sensor. It will cease operation should the internal temperature of the coil exceed

140°C.

- *Neck pain, headache, and dental pain*: Head and neck pain related to stimulation of the underlying muscle and nerves occurs in approximately 10% of subjects. The incidence and severity is a function of stimulus site and intensity, but is most common over fronto-temporal regions. The symptoms are self-limited and usually treated with minor over-the-counter analgesics.

- *Exposure to magnetic fields*: The maximal field strength generated by commercially available stimulators, such as the Magstim device that will be used in this study, is in the 2-Tesla range. The field is induced for a brief period only, and the strength of the field falls off rapidly with distance from the coil. There is no evidence of any acute adverse effects from magnetic field exposure; however, the long-term effects of exposure to rTMS are unknown.

The procedures used in this study may cause all, some, or none of the side effects listed. There may be other side effects of the procedures that we do not know of yet.

Potential Benefits: It is not known if this treatment will help you or not. If the treatment is successful, you might benefit from active rTMS such that your quit attempt is more comfortable, and you may be more likely to succeed in quitting smoking. You understand that there is no guarantee that being on the study will help you. Others trying to quit smoking may be helped from the results and information gained from this study.

Other Options: If you do not join this study, there are a number of effective stop-smoking treatments to choose from. Other treatments include:

1. Nicotine replacement therapy
2. Buroprion
3. Varenicline
4. Behavioral counseling through the state-funded telephone Quitline, which is free of charge

The type of study, the risks, benefits, discomforts, and other important information about this study are discussed below.

ADDITIONAL INFORMATION ABOUT THIS RESEARCH STUDY

It is important that you read and understand the following facts that apply to anyone that takes part in our studies:

a) This study is considered research. It is investigational.

b) Taking part in the study is voluntary.

c) You may withdraw from the study at any time without penalty, loss of any benefits or access to care at Roswell Park to which you are otherwise entitled.

d) If you should decide not to take part in this study, it will not affect your care at Roswell Park now or in the future.

e) You may not stop smoking related to taking part in this study, but we may get information that will help others.

f) If we become aware of important new information that may relate to your willingness to participate in this study, we will inform you of this new information.

1. What is the purpose of this study?

The purpose of this study is to determine a dosing strategy for 20Hz rTMS that will produce the best long-term abstinence outcomes with the fewest undesirable side effects.

2. What are the study groups?

The study involves random (by chance) placement into one of the treatment arms. Neither you nor the researcher can choose the group or arm you will be placed in. A statistician will use a computer to assign the groups. By using randomization, the groups will be similar and the treatments they receive can be compared objectively. You will have an equal chance of being placed in each group. Stratification is sorting people according to various characteristics before randomization. Participants in this study will be stratified by nicotine dependence level.

The possible treatment arms that you could be placed into are:

- 8 stimulation days, once per day
- 8 stimulation days, twice per day
- 12 stimulation days, once per day
- 12 stimulation days, twice per day
- 16 stimulation days, once per day
- 16 stimulation days, twice per day

There is an active and a sham (placebo) for each condition. The sham (placebo) feels the same as the active treatments, except that the pulses are not strong enough to have any effect. Both the sham and active treatment conditions will receive the minimum intervention of educational materials and brief structured counseling.

3. If I take part in this study, what exams, tests and procedures will I have done?

Baseline questionnaire including standard demographic, clinical, and tobacco use measures, tests for nicotine dependence, and perceived stress.

We will ask you to complete a urine drug and pregnancy (if applicable) test at baseline. This is to make sure it is safe for you to be treated with rTMS.

Magnetic Resonance Imaging (MRI) of the brain. We will measure your head and place a vitamin capsule outside your forehead at the place where we will stimulate. This will appear as a bright spot on the MRI and help us make sure we are stimulating the exact right spot for your specific brain.

Expired breath carbon monoxide will be measured at baseline, after the quit date (right before your first rTMS session), and at 4-, 8-, 12-, 18-, and 24-weeks after the quit day

You will be asked to complete questionnaires about potential undesirable side effects, motivations to quit, nicotine withdrawal, mood, depression, anxiety, willingness to engage in treatment, delay discounting, and tobacco use measures at baseline, after each treatment session, and at 4-, 8-, 12-, 18-, and 24-weeks after the quit day.

4. Will I be informed of research results?

If we learn new information from the MRI that we believe may be important to your health, we will share that information with you and we will provide a referral for follow-up with an appropriate medical specialist if abnormalities are discovered in your MRI.

5. Why would I be taken off the study early?

You may be taken off the study for any of the following reasons:

- A serious or unexpected adverse event occurs
- You exhibit emergence of unstable psychopathology or any significant medical disorder
- You do not follow the study schedule or requirements
- You experience unacceptable side effects
- You no longer want to participate

6. What risks and discomforts are involved?

While you take part in this study, you are at risk for side effects. The side effects may be mild, moderate, or severe. Many side effects go away shortly after the treatment stops. It is not possible to tell which side effect will affect you or how mild or severe the side effect might be. We can only tell you what other people have experienced.

It is very important that you notify the study team right away about **any** side effects, problems, or unusual experiences you may have while undergoing this procedure. This will decrease the chance that the side effects continue or become worse.

The most common side effects of the MRI are:

- *Anxiety*: Some people might experience anxiety during the scanning process. MRI scans are performed in small enclosures that could cause anxiety. Participants will spend up to 30 minutes in this enclosure.
- *Incidental MRI findings*: A radiologist reads each MRI scan to ensure safe participation in the study and rule out brain abnormalities. MRI scans can reveal an undiagnosed brain abnormality that would exclude the participant from study but might also bring awareness of a previously unknown brain abnormality that might be quite serious (e.g., tumor, aneurism, etc.) and for which treatment is risky. Any findings from the MRI scan will be made known to you and we will provide a referral for follow-up with an appropriate medical specialist if abnormalities are discovered.

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The procedures used in this study may cause all, some, or none of the side effects listed. There may be other side effects of the procedures that we do not know of yet.

7. Reproductive Risks

This study may involve risks to you or your unborn child that are not known at this time therefore, you should not become pregnant or father a baby while you are participating in this study. Also, you should not nurse your baby while on this study. If you plan to have children in the future, discuss with your doctor whether it may be necessary to have your eggs or sperm preserved prior to participating in this study. Women of childbearing potential will be required to take a pregnancy test before being allowed to take part in this study. The pregnancy test must be negative before you enter this study.

Women of childbearing potential will be asked to practice an effective method of birth control while on this study and for a time after treatment ends. This includes, but is not limited to, oral birth control pills, an IUD, condoms with spermicide, or abstinence. Male patients must use an effective method of birth control. This can include, but is not limited to, condoms with spermicide, abstinence, or having a vasectomy.

When you sign this consent form, to the best of your knowledge, you are not pregnant and do not plan to become pregnant while taking part in this study. Should you become pregnant during this study, you need to immediately tell your study doctor and obstetrician. If you wish you may request a referral for counseling or ask about counseling (such as genetic counselor, social worker, or psychologist.) to discuss this further.

8. What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments.
- Tell the study team about:
  - all medications and supplements you are taking.
  - any side effects.
  - any doctors' visits or hospital stays outside of this study.
  - if you have been or are currently in another research study.

9. Who should I contact with questions about costs related to this study?

Examinations, scans, laboratory tests, and other medical procedures and treatment that are required only for the research study are known as "research related services." Research related services will **not** be charged to you or to your insurance. If you receive a bill in error, please contact the study team immediately.

10. What happens if I am injured as a result of this study?

If you believe you have been injured as a direct result of your participation in this research study, notify the Roswell Park Patient Advocate at 716-845-1365 or the Study Doctor at 716-845-1186.

If you develop complications or side effects from your participation in this clinical research study, medical treatment and/or medications to help with side effects will be provided at the usual charge and will be billed to you and /or your insurance company.

Medical diagnosis and treatment for the injury will be offered, and a determination will be made regarding appropriate billing for the diagnosis and treatment of the injury. A financial counselor can be reached at 716-845-4782 to provide an explanation of coverage and to answer questions you may have regarding study related billing.

You do not give up any legal rights by signing this form. You are not prevented from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

11. Will I be paid for joining this study?

You will receive the following payment(s) for participating in this study:

$20 for each visit – baseline, MRI, stimulation visits (8-32), and 5 outcome assessments

$50 bonus at the end of each week if you complete all assigned stimulation sessions in that week.

$100 bonus if you attend all 5 outcome assessments.

In order to issue you payment, Roswell Park will need to collect from you an Internal Revenue Service (IRS) W-9 form including your name, address and Social Security Number. If you receive $600 or more in a calendar year for your participation in this study, Roswell Park must report the amount you receive to the Internal Revenue Service (IRS) on the form 1099-MISC. This form tells the IRS that payment was made to you, but it does not say that you were paid for taking part in this research study. You should talk to your tax advisor regarding the proper use of this form 1099-MISC in preparing your taxes.

It is possible that this research project may result in developing treatments, devices, new drugs, or procedures that could be used for commercial profit by the sponsor or other entities. If this happens, you understand that you will not receive any financial payment or share in any commercial profit for the use of your information and biospecimens (such as blood or tissue samples) collected as part of this research.

12. Where can I find more information?

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.

13. Who do I contact with questions?

You are free to ask questions at any time about this study and to ask for more information from the doctor identified on this document. If you have any questions, concerns or complaints about this study, you should contact the study doctor identified on the first page of this document. In

case of an emergency after regular hospital hours, you should telephone 716-845-2300 and ask for the Health Behavior Department.

If you have questions about your rights as a research participant or you feel you have been injured as a result of your participation in this research study, you can call the Roswell Park Patient Advocate (Support) Office at 716-845-1365. You should also feel free to contact the Patient Advocate Office at any time while considering participation, during participation or once your participation is complete. This office is unaffiliated with any specific research study. They can help you obtain additional information regarding your research participation and your rights as a research subject or how to proceed should you feel you have been injured as a result of your participation. They are available to discuss any problems, concerns, questions or input you may have.

It may be necessary to contact you at a future date regarding new information about the medication or procedures that you have received. For this reason, we ask that you notify the Patient Access office at 716-845-1049 or stop at the Registration Desk in the Lobby of Roswell Park to update us of any change in your address.

14. What about confidentiality of my information?

Your privacy is very important and the study doctors and those involved with this research study will make every effort to protect it.

Some of your health information, such as your response to treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a research database. As required by law, only the minimum, necessary information that identifies you will be used to conduct this research study. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Information that identifies you may be removed from your health information and/or biospecimens (such as blood or tissue samples, if applicable). The de-identified health information or biospecimens may then be used or disclosed for other purposes, including for future research studies or distributed to another investigator for future research studies, without additional informed consent or authorization from you.

Your health information may also be stored in a research database or repository. This information may then be used for other research, either de-identified or identified. Future research studies using your health information will be reviewed by an oversight board known as an Institutional Review Board if required by law. This information will be kept indefinitely.

Sharing information is part of the research process and may increase what we can learn from the research. Researchers share information by putting data from the study into one or more scientific databases, where it is stored along with information from other people and studies; this is referred

to as large scale data sharing. Researchers can then study the combined information to learn even more about health and disease. Often, sharing data is required as a condition of funding or for publishing study results. It is also needed to allow other researchers to validate study findings and to come up with new ideas. There are many different kinds of scientific databases; some are maintained by Roswell Park, some are maintained by the federal government, and some are maintained by private companies. Your name and other information that could readily identify you (such as your address) will not be shared or placed into an external scientific database. All requests for data sharing will be reviewed by Roswell Park and we will use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use the information to identify you.

Certificate of Confidentiality

As an additional measure to protect your privacy, a Certificate of Confidentiality has been issued from the United States Government, National Institutes of Health, for this study. With this Certificate, the investigators and institutions involved in this study 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 proceeding. We will use this Certificate to resist any demands for information that would identify you, with the following exceptions:

- The Certificate cannot be used to resist a request for your information from the United States Government when the information is to be used for auditing or evaluation of federally funded projects or for information that must be disclosed to meet the requirements of the Food and Drug Administration (FDA).
- State law requires we report cases of diseases that spread easily, or abusive behavior (toward a child, a partner, or an elderly person), and people who say they are going to hurt themselves or someone else.
- The Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or involvement in this research. Also, if you have given written consent to an insurer, employer, or other person to receive research information, then we may not use the Certificate to withhold the information.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION

If you volunteer to take part in this research study, and you sign this document, you give permission to the study doctor and research staff to use or disclose (release) your health information that identifies you and is collected as part of the research study described in this consent. This means that others may know or be able to find out your identity, use your health information and share it with others. We want you to know who may use this information and how they may use it. We also want to tell you about your rights before you agree to take part in the study.

If you volunteer to take part in this research study, you consent to the release of your health information from other medical facilities for any moderate to life-threatening or fatal adverse events that occur while on study treatment through 90 days after treatment ends.

Who may see this information?

- Dr. Sheffer and all the members of the study/research team and other health care professionals at Roswell Park.
- The Sponsor of this study, its' affiliates, successor companies, assigns, companies that may buy information from the Sponsor, and business collaborators, individuals and organizations working with the Sponsor and their representatives, including authorized study monitors, auditors and clinical research organization representatives.
- Institutional Review Boards or Data Safety and Monitoring Boards at Roswell Park and its affiliates or outside of Roswell Park.

What information may be collected, used, and shared?

Health information that identifies you and relates to your participation in this study will be collected and created. This may include the following:

- Health information, sometimes known as "Protected Health Information" (PHI) can include your name; address, patient identification number; medical record number; date of birth; photographs; information about your health, including past medical history, treatment, diagnosis, test results and any other information about your health or medical condition; or about payment of charges for medical treatment found in your medical record or other records maintained by Roswell Park.
- Information from the procedures used to find out whether you are eligible to take part in this study. This may include physical examinations, blood and urine tests, x-rays and other procedures or tests, and any other information that you may release to us, including information about your health history.
- Information obtained in the course of the study including information about your response to any treatments you receive, information related to study visits and phone calls, physical examinations, blood and urine tests, genomic or genetic tests, x-rays and other procedures or tests, and any other information about your participation in this study.

Why will this information be used and/or shared?

PHI and other information that may identify you will be used and given out to others to carry out the research study. The sponsor will analyze (test) and evaluate the results of the study. The sponsor, its agents, assigns, government agencies, and others may visit the research site to follow how the study is being done and may review your information for this purpose.

This information may be given to the FDA. It may also be shared with other governmental agencies in this country and in other countries. This is done for participant protection and so the sponsor can receive marketing approval for any new products that may result from this research. The information may also be used to meet the reporting needs of the governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed (shared).

What if I decide not to give permission to use and give out my health information?

If you refuse to authorize the collection, use and disclosure of your health information as indicated above, you will not be able to be in this research study.

Your decision not to sign this authorization or to withdraw from the study will not involve any penalty or loss of benefits to which you are otherwise entitled and will not affect your access to non-research related health care here.

What happens if I want to withdraw my authorization?

You may change your mind and revoke (take back) this authorization at any time, except to the extent that Roswell Park has already acted (used or disclosed health information) based on this authorization. To revoke/withdraw this authorization, you must write to the study doctor (name and address is on the first page of this form) and let the doctor know that you are withdrawing your authorization to use and disclose your information.

If you should die while enrolled in or after taking part in this study, your health information may be used or disclosed solely for research purposes without getting any added authorization.

The results of clinical tests or therapy performed as part of the research may be included in your medical record and will not be removed from the record if you withdraw.

May I review or copy the information obtained from me or created about me?

You may not have the right to review or copy aspects of your Protected Health Information (PHI) that are considered to impact the integrity (truthfulness) of this research study. At the end of this research study and at your written request, you may have access to your health information that relates to the research study. Information is kept in your medical record, which is a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Roswell Park to decide about care and treatment. Access to your health information in your medical record is described in the Notice of Privacy Practices provided to you by Roswell Park. If it is necessary for your care and/or treatment, your PHI will be provided to you or your referring or primary care doctor. You will not have access to your blood, tissue, and diagnostic research study results that are performed in a laboratory/facility that is not approved to report clinical results.

When does this authorization end?

This authorization does not have an end date.

What happens to my health information after it is given to others?

If you sign this form, the health information collected from you and shared as indicated above, may be re-disclosed to third parties who are not subject to the same laws as those in the United States and may no longer be protected. There is a risk that your information will be given to others without your permission; however, the Sponsor also has protections in place to assure the security of your health information.

Authorization

As a participant in this study, you agree to allow the use of your health information for research purposes. You understand that your health information will be used/disclosed by Roswell Park as indicated in this document. You understand that you have a right to withdraw your authorization for use of your health information in writing, but the information which has already been used or disclosed before your written withdrawal will continue to be used for research purposes. Finally, you understand your health information that has been disclosed by Roswell Park through this authorization to the study sponsor, government agencies, or others may be further disclosed by them, as the health information will no longer be protected by the federal privacy laws.

Statement of Investigator/Person Conducting the Informed Consent Discussion:

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained and that any questions about this information have been answered. A signed copy of this consent will be given to the participant.

SIGNATURE_____ **DATE**_____ **TIME**_____

PRINTED NAME_____

Participant's Statement of Consent:

By signing below, you agree that:

- You have been told of the reasons for this study.
- You have had the study explained to you.
- You have had all of your questions answered, including those about areas you did not understand, to your satisfaction.
- You have carefully read this consent form and will receive a signed copy of this form.
- You do **not** waive any **legal** rights you have under federal or state laws and regulations.
- You willingly give your consent to voluntarily join in this research study.

Participant:

SIGNATURE_____ **DATE**_____ **TIME**_____

PRINTED NAME_____