INFORMATION FOR RESEARCH PARTICIPANTS

Western Michigan University Homer Stryker M.D. School of Medicine (WMed) Human Research Protection Program (HRPP) is committed to the protection of the rights and welfare of individuals who volunteer for research. Volunteers are also known as "subjects" or "participants." This document includes basic information about research and the rights of research participants.

This information is intended to help you make informed choices if:

- someone from WMed asks you to participate in research,
- you see or hear advertisements for WMed research and think about volunteering,
- you want to participate in research, but you do not know where to start, or
- you are seeking research opportunities for a specific disease/condition.
TABLE OF CONTENTS

GENERAL INFORMATION ABOUT RESEARCH

- What is Research?
- What is a Human Subject?
- What is an Institutional Review Board?
- Biomedical Research
- Clinical Trial Research
  - What is a Clinical Trial?
  - How Does a Clinical Trial Work?
  - What are Potential Benefits of Participating in Clinical Trials?
  - What are Potential Risks of Participating in Clinical Trials?
  - What if I Leave the Study Early?
  - What Safeguards are in Place to Protect Me as a Research Participant?
  - How are My Rights Protected if I Volunteer to Participate in a Clinical Trial?
- Social, Behavioral & Educational Research
  - Examples of Social, Behavioral & Educational Projects
  - What are Potential Benefits of Participating in Social, Behavioral & Educational Research?
  - What are Potential Risks of Participating in Social, Behavioral & Educational Research?
  - What if I Leave the Study Early?
  - What Safeguards are in Place to Protect me as a Research Participant?
  - How are My Rights Protected if I Volunteer to Participate in Social, Behavioral & Educational Research?
- Why is Research Important?
- Who Reviews and Approves Research at WMed?
- Who Watches Over Research While It Is Being Done?
- Where Can I Find More General Information About Research?
- Where Can I Find Potential Research Opportunities for Myself or Others?
- Community Research Educational Opportunities

WHAT YOU SHOULD KNOW BEFORE YOU VOLUNTEER TO PARTICIPATE IN RESEARCH

- What are Participants Commonly Asked to Do?
- What Information Should the Researcher Communicate and/or Provide to Me?
- What Questions Might I Want to Ask Before Agreeing to Participate?
  - About the Research
  - What Would Happen?
  - Risks Involved
  - Privacy and Confidentiality
  - Financial Considerations
  - Additional Considerations
- What Will Happen if I Volunteer for Research at WMed?
- What are the General Benefits of Participating in Research?
- Will I Be Paid for Participating in Research?
- Who Else Will Know That I Am Participating in Research?
- What Happens if I Leave a Study?
- What Happens When the Study Ends?

YOUR RIGHTS AS A RESEARCH STUDY PARTICIPANT

- What Rights Do I Have As a Research Study Participant?
- How Do I Protect My Rights if I Volunteer?
- How Can I Report a Possible Research-Related Concern, Complaint or Violation?
GENERAL INFORMATION ABOUT RESEARCH

What is Research?
- Research is a study that is done to answer a question
- Scientists and Doctors do research because they don’t know for sure what works best to help you.
- Some other words that describe research are clinical trial, protocol, survey, or experiment.
- Research is not the same as treatment.

The faculty, students and staff at WMed conduct research in many different areas.

People might participate in research that is being done to learn more about:

- how or why an illness occurs or spreads
- what treatments work best for an illness
- how people behave or make decisions
- the ways groups and societies are organized
- what people think or believe
- how people learn
- the best ways to provide social services or healthcare

What is a Human Subject?
A human subject is a living individual that an investigator conducting research obtains information through tests, treatments or talking with the person or through that person’s private health information.

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that are not part of the research study team. These include specially trained doctors, scientists, and other people from the local community. An IRB reviews the research plan to make sure people in the research study will be treated fairly and that any risks will be explained to them.

Before a clinical or social behavioral research study can begin, the research plan must be approved by an IRB. You can always reach the WMed IRB by calling 269.337.4345 or use the website irb@med.wmich.edu if you have questions, concerns, or complaints.

Clinical Trial Research

What is a Clinical Trial?
A clinical trial is a strictly controlled research study conducted in people. Each study is carefully designed to answer specific questions about a new treatment or a drug or a medical device to make sure it is safe and effective to use in people.

The details of the clinical trial, including all the tests and procedures used in the study, are outlined in a research plan, also called a protocol. The doctors, nurses and scientists who run the clinical trial must follow the protocol and run the tests according to the strict rules set by the
Food and Drug Administration (FDA) and other government agencies. The rules ensure that people who participate in the clinical trial are treated as safely as possible.

You can find more information about "clinical trials" at ClinicalTrials.gov.

How Does a Clinical Trial Work?

In clinical trials, investigational drugs are often compared with approved drugs or placebo (pill, liquid, or powder that does not have any drugs or medicine) to assess if it is safe or effective. Clinical study participants may be assigned to take:

- Investigational drugs
- Approved drugs
- Placebo
- Any combination of the above

A placebo is a product that does not have any drugs or medicine. The participant, physician, and research staff may not know which participant receives a placebo or which receives the investigational treatment. Not knowing which participants are receiving the actual treatment allows the physician and research staff to impartially observe the participants during the study. Regardless of which treatment participants receive, the level of medical attention and care that each receives is the same.

A drug or device is considered "experimental" because the U.S. Food and Drug Administration (FDA) has not approved it for any use, or to treat a certain illness.

As a research participant, you may be asked to:

- Take investigational drugs as directed
- Come in for your office visits
- Have laboratory and diagnostic tests

What are Potential Benefits of Participating in Clinical Trials?

Participation in clinical research has several potential benefits:

- A chance to take part in clinical research that will help you and the researchers learn more about your condition or disease.
- The chance to receive a new and potentially promising treatment that is not available to the general public.
- The chance to receive care for your condition at leading teaching hospitals and research institutes.
- A chance to take part in clinical research that will hopefully find better ways to prevent and treat diseases in the future.

What are Potential Risks of Participating in Clinical Trials?

Along with benefits, there are potential risks and drawbacks of participating in a clinical research study:

- Your disease or condition may not get better with the experimental treatment.
• You may experience side effects or have a bad reaction to the study treatment you receive
• You may be in a group that gets a placebo (a pill, liquid, or powder that does not have any drugs or medicine). A placebo is like taking a sugar pill and will not affect a disease.
• You may be in a group that gets standard treatment instead of the experimental treatment being studied.
• You may have to visit the doctor more often than you would for regular, standard care. The visits might involve having lab tests and procedures done.

What if I Leave the Study Early?

Being a volunteer in a research study is a choice. Even though you can leave the study if you want to, sometimes the researcher needs to take certain steps so that you can be removed from the study safely. This really matters in studies where it may be dangerous for you to simply stop a study procedure (for example, if you are going to stop taking study drug). You may need to slowly withdraw from the study, or come back for a safety visit to make sure you are OK now that you are out of the study. The researcher may also ask if they can contact you by phone or mail for questions about your health, or new information about the study. However, any information collected about you before your decision to end your participation may be used by the researcher.

What Safeguards are in Place to Protect Me as a Research Participant?

• Ethical guidelines
• Informed Consent
• IRB review

Safeguards in the form of ethical guidelines are both to protect the patient volunteers and to preserve the integrity of the science.

The process of providing information to participants continues throughout the study. To help someone decide whether to participate, members of the research team explain details of the study. The research team provides an informed consent document, which includes such details about the study as its purpose, duration, required procedures, and who to contact for various purposes. The informed consent document also explains risks and potential benefits.

The IRB Committee reviews all research projects submitted by researchers (students, faculty, or staff). The IRB has the authority to approve, require changes to the study procedures, disapprove, suspend or terminate research projects. The IRB functions as a type of “human subjects advocate” whose role is to protect subjects participating in research. You should ask the sponsor or research coordinator whether the research you are considering participating in was reviewed by an IRB.

(Source: www.nih.gov)

How are My Rights Protected if I Volunteer to Participate in a Clinical Trial?

As a participant in a research trial, protecting your rights is one of the most important jobs a researcher has.
Before you enter a trial, you have the right to be given all the information you need to make an informed decision about being in the study. Some example of what you must be told are:

- Why the study is being done
- Your option to withdraw from the study at any time without any penalty and without having to give a reason
- What is expected of you
- What will be done to you for research reasons
- How long you will be in the study
- The bad and good things that could happen to you in the study

You have the right to be given all information in words that you understand.

You also have the right to be given as much time as you need to make your decision.

Another right you have is to ASK QUESTIONS and have a detailed talk about the study with the person asking you to volunteer. That is what helps you make an informed decision about whether to be in a study, or continue once you have said yes. You may ask as many questions as you like, as many times as you like, to make sure you understand what is being told to you. The person who is asking you to be in the study may also ask questions to make sure you

Research participants are encouraged to share their concerns or complaints regarding their involvement in a research study with the investigator or study staff. However, research participants may also report their concerns to the WMmed IRB at 269.337.4345, or by completing the Research Compliance Violation Report Form (http://med.wmich.edu/node/397) or by contacting the Compliance Hotline at 269.337.6505.

**Social, Behavioral & Educational Research**

“Behavioral” is a term that covers a lot of ground. It refers to what people do, as well as what drives them to do things, and it involves psychological processes like emotion. “Social”, on the other hand, reflects on how people interact with each other. This could be in small groups, families, and communities, as well as within populations and in society.

Behavioral and social sciences research helps predict, prevent, and manage illness in individual people and in whole populations. This research also helps people change their behaviors, understand treatments, and learn how to stick with them.

**Examples of Social, Behavioral & Educational Projects:**

- Interviews, focus groups, and surveys
- Studies of existing records
- Observation:
  I. With or without observer interacting
  II. Public information such as vital statistics, motor vehicle registration or court records.
  III. Nonpublic information such as medical or educational records in which the participants are identified.
  IV. Conducted in public places, laboratories, or in private settings like a clinic, therapist's office or participants home.
What are Potential Benefits of Participating in Social, Behavioral & Educational Research?

- Knowledge gained from social and behavioral research may benefit society
- May aid in creating of prevention and intervention programs
- Help to determine ideas to guide policy and practice
- Potential benefits of this type of research may be offering interventions for behavioral, psychological, or physical problems
- All seek knowledge for the public good

What are Potential Risks of Participating in Social, Behavioral & Educational Research?

There may be risks to participating in research studies/projects:

- Possible breach of confidentiality is often the greatest risk to participants in this type of research (reputations or employment may be damaged or jeopardized if confidentiality is not maintained).
- Subjects may feel stress caused by the research questions or procedures. (For example, questions may raise painful memories or unresolved issues. Interviews of survivors of personal or state violence may be stressful.)
- Some of the questions asked in surveys, questionnaires and interviews may be sensitive in nature. If any questions make you feel uncomfortable, you are not required to provide a response.
- Possible psychological, social, or economic harm, discomfort, or inconvenience

What if I Leave the Study Early?

You are free to leave the research study/project at any time for any reason without penalty. However, any information collected before your decision to end your participation may be used.

What Safeguards are in Place to Protect Me as a Research Participant?

- Ethical guidelines
- Informed Consent
- IRB review

Safeguards in the form of ethical guidelines are both to protect the patient volunteers and to preserve the integrity of the science.

The process of providing information to participants continues throughout the study. To help someone decide whether to participate, members of the research team explain details of the study. The research team provides an informed consent document, which includes such details about the study as its purpose, duration, required procedures, and who to contact for various purposes. The informed consent document also explains risks and potential benefits.

The IRB Committee reviews all research projects submitted by researchers (students, faculty, or staff). The IRB has the authority to approve, require changes to the study procedures, disapprove, suspend or terminate research projects. The IRB functions as a type of “human subjects advocate” whose role is to protect subjects participating in research. You should ask the sponsor or research coordinator whether the research you are considering participating in was reviewed by an IRB.

04/17/18
How are My Rights Protected if I Volunteer to Participate in Social, Behavioral & Educational Research?

Always keep in mind that participation in research is voluntary. If you feel like you are being pressured to join or stay in a study, you can always say no. You can leave the research at any time for any reason, and you do not have to explain your decision.

Why is Research Important?

Research has led to important discoveries that make our lives better. Some examples are:

- New drugs to treat cancer, diabetes, and other diseases.
- Ultrasound, X-ray machines, and diagnostic tests
- Vaccines
- Ways to stop smoking
- Improved medical procedures
- Possible behavioral, psychological, or physical interventions
- Creation of Psychological and Social Support Services

Who Reviews and Approves Research at WMed?

The WMed IRB is a committee dedicated to review research to assure the protection of the rights and welfare of human subjects for most social, behavioral and educational research conducted at WMed. However, most industry-sponsored clinical trials are overseen by an independent (central) IRB selected by the sponsor and are required to be approved for use by the assistant dean for Research Compliance.

The WMed IRB members include WMed faculty, staff and members from the community who do not have any ties to WMed. The members consist of both scientists and people who are not scientists.

IRB review and approval of a research proposal/project must take place before the research can begin. The WMed IRB is responsible to make sure that:

- the risks of research are as low as possible
- the risks are reasonable compared to the possible benefits (an IRB looks at possible benefits to both participants and to society)
- participants will be fully informed about the study and expectations before, during and after the research (informed consent process)
- participants will be selected and treated fairly
- privacy and confidentiality are protected
- extra protection is provided to vulnerable people, such as children

WMed also has other committees to review specific issues. Examples of these issues include financial conflicts of interest and the safe use of x-rays and other radiation. The IRBs work closely with these other committees to help protect participants.
Who Watches Over Research While It Is Being Done?

The WMed Human Research Protection Program (HRPP) stays involved even after WMed IRB approves research. The WMed HRPP Education-Quality Improvement Program (E-QIP) conducts on-site reviews of WMed research studies. Some sponsors (organizations that cover the costs of research) inspect the research they support. The government (e.g. FDA) may also inspect research sites and/or IRBs to make sure that participants are being protected and that regulations are being followed.

If a researcher wants to change the plan, the WMed IRB has to review and approve the changes before they are applied (unless immediate changes are needed to protect participants from harm). When problems arise, researchers must report those problems to the WMed IRB. The IRB must also review the research at least once a year to make sure that it is going as planned.

Sometimes medical research studies use special committees (e.g., Data and Safety Monitoring Board) to look at detailed information about the research while the research is going on. These committees follow special rules for stopping a study. A study might be stopped if it meets its goals early or if it looks like the study will not meet its goals. This can also happen if safety problems come up more often than expected or if problems are more serious than expected.

Where Can I Find More General Information About Research?

The websites listed below include general information about research:

- U.S. Office for Human Research Protections
- U.S. Food and Drug Administration
- U.S. National Institutes of Health - Clinical Center
- U.S National Institutes of Health - Clinical Trials.gov

Where Can I Find Potential Research Opportunities for Myself or Others?

- Advertising may appear on television, radio, public transportation and the Internet. Advertising also appears in community newspapers and public areas (bulletin boards, clinic waiting rooms, telephone poles, etc.). Advertising always includes a way to contact the researchers for more information.
- Ask your healthcare providers if they are doing research, or if they might be able to refer you to another researcher or to other sources of information.
- Advocacy groups, interest groups or social organizations often work with researchers who are looking for people with certain characteristics, with a particular disease or from a specific community or group of people.
- ClinicalTrials.gov (a federal government-run registry that lists many clinical trials conducted in the US and around the world. It is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of disease and conditions.)
- Searchclinicaltrials.org (a website run by a non-profit organization called Center for Information and Study on Clinical Research Participation [CISCRP])
- AIDS info (a government-run website that lists hhuman immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS) research)
- The clinical trials website of the National Cancer Institute (listings and information)
• WMed Center for Clinical Research (Currently Enrolling Studies)
  
  http://med.wmich.edu/node/118

• Subjects may be contacted about research study opportunities by their health care
  provider, a research study coordinator or a research team member via phone or letter.
  Subjects may also contact WMed directly if responding to radio, television, or newspaper
  ads or other types of recruitment material

• Contact the WMed IRB directly via e-mail IRB@med.wmich.edu or phone at
  269.337.4345

Community Research Educational Opportunities http://med.wmich.edu/node/287

WHAT YOU SHOULD KNOW BEFORE YOU VOLUNTEER TO PARTICIPATE IN RESEARCH

What are Participants Commonly Asked to Do?

Participants help researchers in many different ways. Depending on the goals of the research,
participants might be asked to do things like:

• take part in interviews (sometimes as part of a group)
• complete questionnaires, tests or special tasks
• allow access to private information (such as medical records or school records)
• let researchers observe behavior
• complete physical, psychological or other kinds of examinations
• give samples of blood, saliva, urine or other materials
• take experimental/investigational drugs or use experimental/investigational medical
  devices
• come in office for research-related visits within certain timeframes per protocol
  requirements
• have diagnostic tests performed required per protocol

What Information Should the Researcher Communicate and/or Provide to Me?

The researcher will usually provide you with the information listed below.

• why the research is being done
• why you are being asked to participate
• how long your participation will last
• what will happen during the research (what you will do, the drugs you will take, etc.)
• how the research is different from your usual medical care (research is not the same as
  treatment)
• any expected risks or discomforts that you might experience
• how information about you will be protected
• any expected benefits
• any expected costs to you or your insurance provider
• what you can do instead of participating, such as what treatments you can take that
  might work for you, and how those treatments compare to the research procedures
• what medical treatment you will get in case of problems
• reasons you might be asked to leave the research
• who can help you with problems or give you more information about the study or your
  rights
If you are concerned about any issue or you do not feel like you have enough information, ask the researcher your questions at any time before, during or after the research. During your participation, you also have the right to be given new information that comes up. This information might include changes to what you will be asked to do, new risks or new treatment options. If you are given new information, you will be asked if you are still willing to participate in the research. New risks or new treatments generally require a participant to sign an amended consent form.

What Questions Might I Want to Ask Before Agreeing to Participate?

Your participation in a research study is completely voluntary and it is your decision to choose whether or not you want to participate. It is important that you have the information needed to make such a decision. To help you prepare questions you may want to ask the researcher, refer to list below of “Questions to Ask When Deciding Whether to Volunteer for Research from the Department of Health and Human Services, U.S. Office for Human Research Protections website (hhs.gov/about-research-participation).

About the Research

- What is the research about and why is it being done?
- What do researchers hope to learn and who might benefit from it?
- Who is funding the study?
- Who has reviewed and approved the study?
- Who is being asked to volunteer to be in the study?
- Why are you, specifically, being asked to participate?
- When is the study expected to be completed?
- How will the findings of the research be shared and would you be informed personally?
- What kind of study is this?
- Is it a clinical trial?
- How many groups (or arms) are there?
- Is assignment to groups randomized, or could you choose?
- Will any of the groups receive a placebo or an inactive treatment?

What Would Happen?

- What would you have to do? What kind of medications, procedures, or tests would you have?
- Will you have to go anywhere to participate in the study?
- Will the study involve a novel or untested intervention that is considered experimental?
- Would you be told if you are given the intervention being tested?
- How long would your participation last?
- Would you be given the results of any study tests or procedures that are done?
- If you have a disease or condition that is being studied in the research and you choose not to participate, what treatments or procedures are available to you? Would you still have access to the research intervention outside of the study?
- If you have a disease or condition that is being studied in the research, ask if your doctor is also a researcher on the study. If so, who would watch out for your best interests as a patient?
- How would being in this study affect your daily life?
- How would being in this study affect your current medical care?
Risks Involved

- How much do the researchers know about the risks of the research intervention—especially if the intervention is new or experimental? Does the intervention have FDA approval or oversight?
- What are the short-term or long-term risks, discomforts, or unpleasant side effects? How likely are they to occur, and are any of them severe?
- What are the researchers doing to minimize risks, discomforts, or unpleasant side effects?
- Is there anything you could do to minimize your risks during the study?

Privacy and Confidentiality

- How would your biological materials (such as blood samples), data (such as test results), or other personal information be used or shared?
- How would your privacy and identifiable private information be protected?
- What could happen to you if your identifiable private information were disclosed to others?

Financial Considerations

- Will participating in the study cost you anything? For example, would you have to pay for certain tests or procedures, or the study drug? If so, what is the estimated cost and would it be covered by health insurance?
- If you were harmed while participating in the study, who would pay for the necessary medical care?
- Will there be any travel or other study-associated costs (for example, childcare) and will researchers provide any money to cover those costs?
- If the research offers financial compensation, how much is offered and when would you receive it?

Additional Considerations

- Would you, personally, benefit from participating in the research? If so, how?
- How much time will you have to think about your options before making a decision?
- If your doctor is also the researcher on the study and you decide not to participate, would this decision affect your current medical care?
- Whom should you contact if you have questions about participating in the research?
- Whom should you contact if you have concerns about the research itself?
- What happens if you volunteer to participate now, but decide to quit the study later?

Remember: You have the right to have all of your questions answered. If you do not understand the answer, please ask the question again.

What Will Happen if I Volunteer for Research at WMed?

You will be presented with information about the study. This is called the informed consent process. Members of the study team, including the researchers, will discuss this information with you. They will usually ask questions to make sure that you understand the information that was discussed.
Once you understand the information and choose to participate, you will be asked to sign the consent form. You might also be asked to sign other documents, such as a form giving permission to use your medical records (HIPAA Authorization).

After you sign the informed consent, the researchers may need to ask some basic questions or perform procedures to make sure you qualify to participate. If you participate in medical research, this may include a physical examination, blood tests or other procedures. This part of the research is called "screening".

Even if you give informed consent, you are not guaranteed a place in the research study. In some cases, researchers can accept anyone who volunteers. In other cases, researchers can accept only a certain number of people or only people who meet the study requirements (inclusion/exclusion criteria).

If you do not qualify, it does not mean something is wrong with you. It just means that you did not meet the study requirements. There might be other studies in which you would qualify to participate.

If you qualify for a study, you will go through the exact steps of the approved research plan. What you undergo during the research should be exactly what is described in the consent form.

What will happen (and for how long) depends on the goals of the research. Sometimes researchers will be able to work around your schedule. In other studies, visits might have to happen at very specific times. All of this should be explained to you during the informed consent process.

**What Are the General Benefits of Participating in Research?**

Researchers are searching for new information and new answers to societal or health-related problems. With these answers, they hope to design solutions or programs, but these solutions take time. Most research is not intended to provide you with direct benefits. When you participate in research, you are, however, contributing to scientific progress and helping society.

**Will I be Paid for Participating in Research?**

Payment will be explained to you during the informed consent process. Some studies do not have the resources to pay you. Other studies might pay you for the time and effort it takes to participate. The money is usually only enough to cover expenses (parking, transportation, meals, etc.) and maybe for some of the time you spend away from work.

The payment should not be significant enough to convince you to take risks that you normally would not take.

If you leave before the end of the research, you will usually be paid for that portion of the research you completed.

**Who Else Will Know that I Am Participating in Research?**

Members of the research team, and when appropriate, others who are involved with your care (primary healthcare provider) or who have permission to see your records, will know that you
are participating in research. It is a good idea to let your primary healthcare provider know that you are participating in a medical research study because s/he will want to know how this affects your medical care. Otherwise, information about your participation is kept confidential unless you choose to tell someone.

What Happens if I Leave a Study?

You always have the right to leave the research at any time and for any reason, and you do not have to explain your decision to anyone. For example, you might feel less comfortable than you thought you would, or maybe the research takes up too much of your time. Nobody should pressure you into staying in the research if you do not want to.

You do not have to, but you might want to discuss any problems with the researcher before leaving. They might not be able to do anything if the research plan is not flexible, but it might be helpful for them to know why you choose not to continue.

What Happens When the Study Ends?

When you complete the study (or if you choose to leave the study early), that is usually the end of your participation except for the possible safety follow-up visit(s). The consent form might describe extra contact(s) by the study team after the study visits have concluded. The researcher might send you information about your participation, including any new information that becomes available that may affect your health. If you were taking an experimental drug, sometimes you may be able to continue taking the drug. You might be asked if you are willing to be contacted about other research in the future.

At the end of the study, the researchers put together all the information they have collected. They will analyze that information. They might be able to publish the results in scientific journals, present the results at conferences and use the results to get grants for more research. Your personal health information will not be included in the resulting publication(s) or presentation(s).

Sometimes the WMed study information will be combined with information from other research sites involved in the study. For an industry-sponsored study, the company who paid for the research may use the information to help get a product approved by the U.S. Food and Drug Administration.

Researchers may or may not be in the position to provide study results at the end of the study. Sometimes it takes many years to achieve study results. You should ask the study investigator about this before you enroll.

YOUR RIGHTS AS A RESEARCH PARTICIPANT

What Rights Do I Have as a Research Study Participant?

The decision as to whether or not you want to participate is an important one and one that should be discussed with your family, friends, and the research team. Your participation in research is completely voluntary and even after agreeing to participate; you may decide to stop at any time. The most important person in the research is the participant. You do not have to participate in any research offered to you.
To help you make an informed decision, you have the right to receive information about the study. Information will almost always be given to you in writing (written study information is called an "informed consent form" or "research information sheet"). The information must always be in a language that you can understand.

WMed is committed to protecting the rights and welfare of people who volunteer for research. As a research study participant, you have the right to:

- Be given adequate time to decide whether or not to be in the research study and to make that decision without any pressure from the people who are conducting the research.
- Refuse to be in the study at all, and to stop participating at any time after you begin the study without penalty. Your decision to participate will not be used as an excuse to hold back any necessary medical treatment.
- Be told what the study is trying to find out, what will happen to you, and what you will be asked to do if you decide to participate in the study.
- Be told about the risk and benefits of any other available procedures, drugs or devices that might be helpful to you.
- Be informed about the possible benefits of being in the study.
- Be informed about the reasonably foreseeable risks of being in the study.
- Ask any questions about the research study or other procedures involved.
- Be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.
- Be given a signed and dated copy of the consent form, when one is required for research.
- Be made aware of who will have access to information collected about you, and how your confidentiality will be protected.
- Be told who to contact with questions about the research, about research-related injury, and about your rights as a research subject.
- Be told about other non-research treatment choices you have if the study involves treatment or therapy.

How Do I Protect My Rights if I Volunteer?

The most important thing to do is take an active role and communicate with the study team before, during and after the research. You should always ask questions if you are not clear about something, if you are curious about something, or if it seems like the research plan is different from what you were told. You have a right to have your questions answered.

Take your time making decisions about whether or not to participate. You should seek the advice of trusted family members, friends or healthcare professionals before and during the research.

If you feel uncomfortable with what you are doing, or if you think you might be experiencing changes in your health (whether good or bad), let the study team know so that they can help you.

Always keep in mind that participation in research is voluntary. If you feel like you are being pressured to join or stay in a study, you can always say no. You can leave the research at any
time for any reason, and you do not have to explain your decision. You may, however, be asked to have certain procedures performed for you to safely withdraw from medical studies.

How Can I Report a Possible Research-Related Concern, Complaint or Violation?

Research participants are encouraged to share their concerns or complaints regarding their involvement in a research study with the investigator or study staff. However, research participants may also report their concerns to the WMed IRB at 269.337.4345, or by completing the Research Compliance Violation Report Form (http://med.wmich.edu/node/397) or by contacting the Compliance Hotline at 269.337.6505.