PHASE 1 RESEARCH PROGRAM

PATIENT AND FAMILY EDUCATION HANDBOOK

At the U, we transform lives through teaching, research, and service.

SYLVESTER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM
PATIENT AND FAMILY ADVISORY COUNCIL
APPROVED

SYLVESTER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM
IN PURSUIT OF *YOUR CURE.*™

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INTRODUCTION

Welcome to Sylvester Comprehensive Cancer Center!

Welcome to the University of Miami, Sylvester Comprehensive Cancer Center, Phase 1/Experimental Therapeutics (ET) Research Program. Our team of professionals will take you through your clinical trial journey. Our goal is to provide you with the highest quality of care, with the support of our multi-specialty care team, guided by evidence-based research.

The Sylvester Comprehensive Cancer Center is the only University based cancer center in South Florida. The cancer center opened its door in 1973 and was recognized as a Cancer Center of Excellence by the state of Florida in 2015. It has more than 130 cancer specialists and 115 cancer researchers. Our staff works with researchers from colleges across Miami, both nationally and internationally.

This phase 1 research handbook was written with the purpose of providing education to patients in order to:

- Prepare you for participation in a phase 1/ET clinical trial
- Serve as a resource for you and your caregivers
- Help you understand the nature of your treatment

With this information, we believe you will be better prepared to make well-informed decisions with your medical team. That process will help lead to better outcomes for you.

We would like to thank you in advance for choosing Sylvester Comprehensive Cancer Center Phase 1/ET Research Program and for allowing us to be a part of your care.

PHASE 1/EXPERIMENTAL THERAPEUTICS CLINICAL TRIAL BASICS

What is a clinical trial?

A clinical trial is a research study that involves people. These studies help doctors find new ways to treat cancer, to diagnose cancer, and prevent cancer. They aim to manage the symptoms of cancer and side effects from treatment. At Sylvester, we focus on finding new treatments and improving the quality of life for people living with cancer.

Clinical trials begin in a research laboratory setting. Before new treatments can be used with humans, the treatments are tested in labs using animals. They do this to see how well the treatments work and to try to understand the possible side effects related to the treatment.

Before a new cancer treatment can be approved and become part of standard treatment, it must go through three different levels of evaluation called phases;
Phase 1 clinical trials determine whether a new treatment is safe, what its side effects are, and what the best dose to administer is. In addition, they evaluate early evidence of activity and effectiveness.
Phase 2 clinical trials determine if the new treatment has an effect on a certain type of cancer.
Phase 3 clinical trials establish if the new treatment is better than the treatments currently available.
A clinical trials may be are available to individuals with any stage of a disease. For phase 1 studies, the number of participants vary; however, the amount is limited.

All trials have someone in charge, usually the hematologist/oncologist, and they are known as the principal investigator (PI) for the clinical trial. The PI prepares the patient's plan. The protocol is the specific outline of all of the steps that take place during the trial. The protocol may be written by the PI or by the sponsor/company paying for the trial. It explains in detail the following information:

- The reason for the trial
- Who can join
- How many people are needed for the trial
- Any medications given and how often
- The dose and how they will be given
- Any medical testing and how often
- Possible side effects
- What kind of information will be collected about the people who are part of the study

Safety Considerations:

All trials follow strict guidelines in order to protect patients. Federal guidelines are in place to be sure studies are conducted in an ethical manner. Before a study can begin, it must be reviewed and approved by several committees within the University of Miami and Sylvester Comprehensive Cancer Center. These committees review all aspects of the project and make sure patients' rights and information are fully protected.

Once the study is approved, each potential participant must be screened in order to determine if he/she is eligible for the study. Sometimes patients have other medical conditions that could become worse from taking part in a clinical trial. In this case, you will have medical testing done such as

laboratory samples, scans and/or other testing before you participate. This is done to be sure the study is safe for you. Sometimes you have had other treatment(s) for your cancer and the principal investigator (PI) will determine if you are able to participate in a specific study afterward. This is to help the investigators know if results from the experimental treatment are related to that treatment rather than effects from treatment you have received in the past.

Informed Consent:

The informed consent is a process through which you will learn all about the reason for the study as well as the risks and benefits associated with participation. This is reviewed before you decide to sign up for the study. It is important because the information learned in this process will help you decide if this is the right study for you. You will meet with your research coordinator, the advanced practice provider and/or your primary hematologist/oncologist to go over the consent process. They will be there to answer all of your questions related to the study.

You will then decide if you want to take part in the study or not. You will sign the document called "informed consent form" if you choose to participate. If not, that is also ok; you will not have any further contact from the team regarding this study. You may decide to participate in the study and then later on change your mind. You are free to withdrawal or drop out of the study at any point in time without any negative consequences. You simply need to inform either the clinical coordinator, advanced practice professional or primary hematologist/oncologist of your decision to drop out of the study. At that time, your doctor will inform you of other options for treatment available to you.

Financial Considerations for Clinical Trials:

Costs vary from trial to trial. Typically, Phase 1 studies include patient care costs, which are usually covered by your health insurance, and research costs that are covered by the study sponsor. Official clinical trial costs will be provided in detail by your phase 1 study team.

Questions to Ask:

If you are thinking about participating in a clinical trial here at Sylvester Comprehensive Cancer Center, here are some questions that may help you decide:

- **Why is this trial being done?**
- **Why is this treatment possibly better than the current standard of care? Why may it not be better?**
- **How long will I be in the trial?**
- **What extra tests/treatments are involved?**
- **What are the possible side effects of the experimental treatment?**
- **What are some possible benefits?**
- **How will we know if the treatment is working?**
- **Will I have to pay for any treatments or tests?**
- **Will my insurance cover any costs?**
- **How could this trial affect my daily life?**
- **How often will I need to come to the clinic for visits?**
- **Will I have to travel long distances to be a part of this study?**
- **What are my other treatment options?**
- **How does my treatment in this study compare to standard treatment I would receive?**

What to Expect When You Come in For Treatment:

Treatment days tend to be longer days. We can assure you the wait time is due to safety checks built into the procedures to protect you; and we do our best to expedite the process as much as possible.

Arrival
- Doctor's visit
- Labs
- Results are reviewed by MD/ARNP and "ok to treat" is given

Prep
- Study Coordinator alerts the sponsor that you are "ok" to receive treatment today
- Sponsor releases medication to the pharmacy
- Pharmacist hand mixes any IV medications and prepares oral tablets for delivery

Treat
- Pharmacy delivers medications to Study Coordinator in CTU
- RN administers medications to you
- MD/ARNP meet and assess you in CTU or following your treatment in the clinic

Complete
- RN completes treatment, removes access (port/IV), takes vital signs
- Next visits are scheduled with Study Coordinator

At times, you will need additional treatment before or after your study medications are administered. This is dependent upon your laboratory results. These treatments may include electrolyte replacement (i.e. potassium, magnesium, calcium), blood products (i.e. packed red cells, platelets), or medications to address any reactions (i.e. Benadryl®, Tylenol®).

When you need to receive blood products additional time may be spent waiting for them to arrive from the blood bank. Again, this is due to a set of safety procedures in place to protect you from receiving the wrong blood type or product.

Additionally, on certain treatment days, you will need to have labs drawn at certain times based on the sponsor's needs. This will likely add several hours to your visit when this data is required.
You will also have an assessment with your physician and/or the advance practice provider. They will be available along with your study coordinator to answer any questions you may have.
We recommend that you bring a bag with a small blanket, a book, music, tablet/laptop, and snacks to keep you occupied during the down time.

Treatment day processes are subject to change based on your phase 1 clinical trial study.

HELPFUL INFORMATION

Your Phase 1 ET Research Team

The Phase 1/ET Research Team is comprised of many health care professionals who are dedicated to assisting you through the research process. The following is a list of team members and their roles. You will meet each member at different times during your participation in a clinical trial.

- **Referring Hematologist/Oncologist**
  The referring hematologist/oncologist is the physician that has been overseeing your care and has referred you to participate in a Phase I/ET clinical trial. This is a physician who has specialized training in the management of individuals with hematological/oncological disorders. This physician is typically from within the University of Miami cancer center or from the community.

- **Primary Investigator (PI)**
  The primary investigator is a hematologist/oncologist that will be overseeing your care while you are on a clinical trial.

- **Advanced Practice Provider**
  The advanced practice provider is either a nurse practitioner or physician assistant who will be responsible for your care in the clinic setting. If during the course of your clinical trial you should become hospitalized, the advanced practice provider will also see you in the hospital. The advanced practice provider will assess your condition, review your plan of care and continue to collaborate with your primary hematologist/oncologist.

- **Clinical Research Coordinators**
  Your coordinator will be your primary contact for you, your family, and primary physician/advanced practice provider during your time on the trial. She/he will be present at all your clinic visits as and is responsible for making sure that all of the study activities are scheduled and completed according to protocol.

- **Research Triage Nurse**
  The research triage nurse is a Registered Nurse trained to care for hematology/oncology patients on clinical trials. The triage nurse will listen to any medical questions/concerns you have and will provide you with specific instructions and/or discuss the situation with your advanced practice provider or primary hematologist/oncologist if needed, to address your medical questions/concerns.

- **Outpatient Clinic Nurses**
  The nurses are either Licensed Practical Nurses or Registered Nurses trained to care for hematology/oncology patients. They will be caring for you on a regular basis during your clinic visits and will contact an advanced practice provider or physician if needed during that time.

- **Research Clinic Nurses**
  The nurses are Registered Nurses trained to care for hematology/oncology patients. They will be caring for you on a regular basis during your visits for your medication administration

and will be able to contact an advanced practice provider or physician if needed during that time.

- **Research Clinical Pharmacist**
  The Research Clinical Pharmacist works with the phase 1/ET research team and is responsible for the management of medications for patients participating in clinical trials. They will work with your doctor to come up with an appropriate dose for your medication and monitor your medications throughout the clinical trial.

- **Administrative Assistant**
  This person is a contact for the PI or referring physician and Advance Practice Provider. You may contact this person if you need to connect to your providers.

- **Palliative Care Services**
  The Palliative Care team assists patients in managing symptoms associated with cancer. For example, they will provide a treatment plan for a patient experiencing pain that is not well controlled. This team consists of 2-3 physicians and an advance practice professional who have specialized training in the management of individuals with hematological/oncological disorders, with an additional specialty training in the area of palliative care. This team is available to support you throughout your treatment to help manage any symptoms you may be experiencing. This is not the same service as hospice; these services are aimed at relieving pain and providing comfort while you continue treatment.

- **Licensed Clinical Social Worker**
  There are designated clinical social workers assigned to work with patients enrolled in clinical trials. You can request a consult to see the social worker at any time. The social worker can provide supportive counseling, discharge planning, referrals to community resources, and assistance with financial concerns. You can contact a social worker by calling the Courtelis Center for Psychosocial Oncology at (305)-243-4129.

Facility Services

Parking

Valet parking is available at UMHC/SCCC 14th avenue entrance and on the north side of UMHC. For outpatient visits, you will obtain validation for valet parking through your Clinical Research Coordinator or when you are receiving treatment in the Chemotherapy Treatment Unit (CTU).

Cancer Support Services

At Sylvester Comprehensive Cancer Center, we aim to address the patient from a holistic and comprehensive approach. We offer a variety of supportive services for patients including:

- **Acupuncture**
- **Massage Therapy**
- **Music Therapy**
- **Arts in Medicine**
- **Chaplain Services**

- **Exercise Physiology**
- **Nutrition Consultations**
- **Palliative Care**
- **Social Work**
- **Psychosocial Oncology**

For more information or to schedule a visit, please contact: Cancer Support Services at (305)-243-4129.

Patient Experience

The Patient Experience staff assists patients so they can smoothly navigate the treatment process. They focus on problem solving, addressing patient concerns, as well as explaining Sylvester's processes and procedures.

Patient representatives serve as advocates on behalf of our patients to offer the highest quality of care and satisfaction. They work diligently to ensure patients have seamless access to Sylvester services. This includes providing assistance for the hearing impaired and disabled, as well as translation services for those patients who do not speak English. They also address any complaints and assist in service recovery efforts to make the experience enjoyable.
Patient Experience: (305) 243-3820

OTHER CONSIDERATIONS

Advanced Directives

What are Advance Directives?
Advance Directives are written statements that allow you to make your healthcare wishes and preferences known in case you are not able to voice them in the future. These directives may include the type of care you would or would not want and who you would want to make decisions for you, if you are not able. These documents are available at UM/Sylvester and are strongly recommended as part of your treatment process. These documents can be changed or canceled at any time.
Types of Advance Directives available at UM/Sylvester:

- **Healthcare Surrogate Designation:** This form also allows you to identify someone to make your healthcare decisions in the event you are unable to do so.

- **Living Will Declaration:** This document gives you the chance to indicate the kind of life sustaining or life prolonging care you would or would not want in the event you are in a terminal or vegetative state with no hope of recovery, as determined by your doctor.

A social worker can assist you in answering any related questions or completing these documents.

MORE INFORMATION

Hotels and Accommodations

Many hotels, car rental companies and airlines offer discounted rates to Sylvester's patients and guests. There are resources that may help with lodging issues as the American Cancer Society or Joe's House. Contact your social worker if you need help arranging these or other services. The social worker can help coordinate these services and provide other resources that might be helpful through your treatment.

American Cancer Society
www.acs.org
1-800-227-2345

Joe's House
www.joeshouse.org
877-563-7468

Websites

These are websites that may be helpful for patients participating in phase 1/ET trials.

Cancer.net	www.cancer.net
American Cancer Society	www.cancer.org
NIH National Cancer Institute	www.cancer.gov
Leukemia and Lymphoma Society	www.lls.org
International Myeloma Foundation	www.myeloma.org
Multiple Myeloma Research Foundation	www.themmrf.org
Medline Plus	www.medlineplus.gov
American Society of Hematology	www.hematology.org/Patients
NIH Clinical Trials	www.clinicaltrials.gov
American Society of Clinical Oncology	www.asco.org
Myelodysplastic Syndromes Foundation	www.mds-foundation.org