PERSONAL CONSIDERATIONS IN THE DECISION TO PARTICIPATE IN A CLINICAL TRIAL

The decision to participate in a clinical trial should be a thoughtful process in which patients carefully evaluate many aspects of the clinical trial option.

Requirement for Medical Tests

Am I willing to undergo extra testing that may be required, such as bone marrow biopsies, CT scans and frequent blood tests?

For WM, bone marrow biopsies are routinely required before the trial, possibly at an interval during the trial and at completion. CT scans of chest and abdomen are routinely required at the beginning of the trial and depending on protocol and patient results, may be required at intervals and end of trial. Blood tests may be more frequent than during standard care.

Requirement for Travel

Am I able and willing to travel for treatment and testing?

Except for rare occasions, out-of-pocket travel expense is typically not covered by the trial sponsor. In the US, the following organizations may help:

1) **Angel Flight** is a non-profit organization of pilots, volunteers and friends who will arrange free air transportation for medical treatment. Volunteer pilots donate the use of their airplanes and operating expenses. For details: www.angelflight.com.
2) **Corporate Angel Network** is a non-profit organization that arranges free air travel for cancer patients to treatment centers by using empty seats on corporate business flights. For details: www.corpangelnetwork.org.
3) **American Cancer Society** provides Hope Lodges in 31 locations in US. These are free home-like housing options for cancer patients and caregivers. For information: www.cancer.org and type Hope Lodge in search box or call 1-800-227-2345. Free or reduced cost housing may be available through the local **cancer facility**.

Insurance Coverage

If my health insurance does not cover the cost of additional testing in a trial, does the trial sponsor pay for the cost? Does my health insurance cover routine testing and treatments other than the trial drug during a trial?

These questions should be addressed before entering a clinical trial.

Unknown Risks of Experimental Treatment

Am I able to cope with the uncertainty of unknown risks of the trial drug?

Participants are requested to report any unfavorable symptom experienced during the trial. An undesirable change in the participant's health status from immediately prior to taking the trial drug is noted as an **adverse event**. The adverse event is noted as **serious** if it results in a life-threatening situation, hospitalization, disability or death. These events are recorded, monitored carefully with appropriate treatment.

Protection of Participant Rights during a Clinical Trial

How are my rights protected during a clinical trial?

Every clinical trial participant is involved in an informed consent process that includes discussion of all aspects of the trial – purpose, requirements, risks, benefits and right of withdrawal at any time during the trial. Participants sign and receive an informed consent document that is a detailed description of the clinical trial.

Pros and Cons of Clinical Trial vs Standard Care

How do I make a treatment decision?

Considerations:

1) Discuss options with primary oncologist and trial investigator to obtain a wide range of opinions regarding risks and benefits;
2) Evaluate potential treatment risks in relation to personal health issues and quality of life concerns in a shared decision-making process with oncologist;
3) Research treatment options through various websites, such as www.pubmed.gov, www.iwmf.com and www.bingcenterforwm.org and other internet searches.

Eligibility for Clinical Trial

What types of eligibility issues could be a barrier for me entering a specific clinical trial?

Possible exclusion criteria may include: 1) certain chronic health problems; 2) blood count limits; 3) prior treatment for trials specifying untreated patients or limit on number of prior treatments for trials designated for relapsed/refractory patients; and 4) prior treatment with drug in same class as trial drug.

Continuation of Treatment Beyond Clinical Trial

If the drug is working for me, can I continue treatment after the end of the trial?

This is an important question to ask as many newer drugs involve ongoing treatment.