

## HEPATITIS C THERAPY

### STATEMENT OF UNDERSTANDING

The following information has been developed for patients who will be starting therapy for Hepatitis C. The information includes risks and discomforts of Hepatitis C therapy. It is very important for you to read this and ask questions so that you understand what you can expect over the course of your treatment. It is our goal to inform you to the best of our ability and knowledge before you agree to begin therapy. You will be asked to sign this document and a copy will be given to you.

#### **Ribavirin Treatment**

Ribavirin is taken orally. The most common side effect of Ribavirin is hemolytic anemia. As a result, there are less red blood cells that carry oxygen to the tissues in your body. This condition is more common in older than in younger patients, and the anemia is often accompanied by a slight increase in bilirubin (a reddish-yellow pigment that is normally found in blood and urine). The anemia is usually mild and improves with dose reduction of Ribavirin. Anemia resolves once Ribavirin Therapy is discontinued. The anemia can be serious in patients who have kidney and/or heart problems as anemia can make these conditions worse. Heart and/or lung problems associated with anemia occur in a small percentage of patients on Ribavirin Therapy. Frequent blood tests are crucial to evaluate this anemia. You will be asked to keep your appointments and have your blood drawn at each visit. You will not be given any more medication until your blood is drawn and your results are reviewed. This is very important for your health and will help determine if your Ribavirin dose should be reduced.

Other side effects that are common with Ribavirin include gout (a disease associated with increased amounts of uric acid in the blood and painful inflammation in the joints) and effects on the nervous system such as depression, nervousness, insomnia (difficulty in sleeping) and dizziness.

If at any time during treatment you are not able to tolerate these side effects, the Ribavirin dose will be reduced, interrupted, or discontinued.

Studies in animals have shown that when Ribavirin is given to pregnant females, malformations in the offspring or death of the developing embryo may occur. It is unknown if interferons can cause problems with pregnancy or birth defects.

**Therefore, these therapies must not be used by women or male partners of women who are or may become pregnant during therapy and during the six months after stopping therapy. It is important that both men and women on Ribavirin and/or Interferons use at least two forms of effective birth control (example: condom plus birth control pill etc.) or avoid sexual intercourse completely during treatment and for six months after completion of treatment so that pregnancy does not occur.**

#### **All Patients**

During the treatment and follow-up periods, lab test and medical visits are required regularly. These visits are very important in order to check your blood chemistry, pregnancy status, and liver, heart and thyroid functions. You will also have a random blood/urine screens to check for

drugs and alcohol in your system. Ongoing evaluation for depression and other mood disturbances while on treatment is vital.

Signed \_\_\_\_\_ Date: \_\_\_\_\_

Witness \_\_\_\_\_ Date: \_\_\_\_\_