Informed Consent Bisphosphonate Class of Drugs

I have in the past or are currently taking a bisphosphonate drug. These drug(s) may include: Currently taking/ last taken (circle one)

- ❑ Fosamax® (Alendronate)
- ❑ Fosamax Plus D™ (Alendronate and Cholecalciferol)
- ❑ Bonefos®; Clasteon®; Ostac® (Clodronate)
- ❑ Didrocal™ (Etidronate and Calcium)
- ❑ Didronel® (Etidronate Disodium)
- ❑ Boniva® (Ibandronate)
- ❑ Aredia® (Pamidronate)
- ❑ Actonel® (Risedronate, Risedronate and Calcium)
- ❑ Skelid® (Tiludronate)
- ❑ Reclast®; Zometa® (Zoledronic Acid)
- ❑ Other_____

___/___/___ Date

I understand these drugs are commonly used for several medical purposes including but not limited to prevention and treatment of certain cancers, treatment of Paget's Disease of Bone, prevention and treatment of osteoporosis and malignancies with bony metastasis like multiple myeloma, and several other diseases. These drugs slow down the cellular activity necessary for bone remodeling. This results in decreased new bone formation and reduced blood vessel ingrowths into the bone. Because the bisphosphonates are preferentially deposited in bone with high turnover rates, the jaw is particularly affected by these drugs. Bisphosphonate also are not metabolized, high concentrations remain within the bone for a long period of time.

I understand having been treated previously or currently with Bisphosphonates there is a risk with a condition called Bisphosphonate-Associated Osteonecrosis of the jaws (ONJ), though very low and questionable. This risk is increased after surgery, especially with extraction, implant placement, periodontal scaling and root planning or other "invasive" procedure that might cause trauma to bone. Osteonecrosis, or dead bone, may result. This is a long term, destructive process in the jawbone that is often very difficult or impossible to eliminate.

I understand from the research that the potential risk factors include but not limited to:

1. Risk is lower for those that have or are taking oral bisphosphonates.
2. Recent trauma (tooth extraction, implant placement, jaw surgery) is the most prevalent, consistent risk factor reported.
3. Longer treatment with bisphosphonates is associated with a higher risk of developing osteonecrosis.
4. The more potent IV bisphosphonates (Aredia, Zometa, Bonefos) are much higher risks therefore referred to a specialist.

I understand despite all precautions, there may be delayed healing that could result in osteonecrosis, loss of bone and soft tissues, pathologic fracture of the jaw, or other significant complications. Treatment strategies may include;

- Antibacterial mouth rinses.
- Routine clinical follow-up at 3 month intervals.
- Antibiotic therapy and pain control.
- Superficial surgical debridement to relieve soft tissue irritation
- Surgical debridement/resection for longer term control of infection and pain.
- Hospitalization/Reconstructive surgery including bone grafting, metal plates and screws, and/or skin flaps and grafts.

I understand even if there are no immediate complications from the proposed dental treatment, the area is always subject to spontaneous breakdown and infection. The symptoms of ONJ also known as BON, may include ulceration of the oral mucosa, altered sensation (possibly numbness), infection, pain, soft tissue swelling, loosening of the teeth, numbness, sloughing or fracture in the affected jaw, drainage and exposed bone. This condition may remain asymptomatic for many weeks or months and may only be recognized by the presence of pain or exposed bone in the mouth. Even minimal trauma from a toothbrush, chewing hard food, or denture sores may trigger a complication.

I understand the possible risks of undergoing my planned treatment. I understand and agree to the dental treatment plan. I agree to consultation with my medical doctor or oncologist to determine the relative risk for developing ONJ and request a CTX fasting blood test in order to evaluate, though not definitive, the risk of osteonecrosis. Recommendations of CTX results are:

<**100**pg/ml= High Risk **100-150**=Moderate Risk >**151**=Little to No Risk

I understand, based on research, that if I have been taking an oral bisphosphonate for <3 years my doctor may treat as necessary and if bisphosphonate therapy has been >3 years a recommendation of discontinuing my bisphosphonate (with medical doctor collaboration) for 3 months prior to planned dental procedure. As a guideline CTX values were noted to increase for each month of a "drug holiday" indicating recovery of bone remodeling. I agree to CTX test as needed. Once the dental treatment is completed extension of the "drug holiday" for an additional 3 months is recommended. I understand the potential risks, complications and side effects involved with this procedure and have decided to proceed.

_____ _____

Signature of Patient or Guardian **Date**

_____ _____

Signature of Witness **Date**

_____ _____

Signature of Doctor **Date**