Date:\_\_\_\_\_\_ Pt # \_\_\_\_\_

**Informed Consent for Obtaining Blood Samples in Patients with Osteonecrosis of the Jaw**

**Research Study:** Are Pathogenetic Coagulation Proteins Operative in the Development of

Osteonecrosis of the Jaw?

**Reason for Study:**

The cause of your jaw problem (osteonecrosis of the jaw) is not completely understood. We do not know if certain medications used to treat osteoporosis, arthritis and some cancers can adversely affect the circulation within the jaw. Only a few patients taking these medications develop osteonecrosis. We want to find out why these patients have this condition, while many others do not. This research project will determine if you have a genetic predisposition to form “super clots”, which may act as an additional risk factor for the development of your diseased jaw. This could be important to you because:

1. Knowledge that you have abnormal clotting factors could result in treatment with blood thinners. Blood thinners could prevent or slow down further deterioration of your jaw.
2. If you have this genetic clotting disorder, you, your siblings, your children and your grandchildren are at increased risk of developing clots in certain clinical situations, e.g. during long distance traveling, post-op surgical complications such as blood clots in your legs, lungs, brain (stroke), etc. Similar complications are also associated with the use of birth control pills, estrogen replacement therapy, fertility drugs, also pregnancy, etc.
3. You and your blood relatives would also have a greater propensity to develop jaw necrosis if he or she has any of these abnormal clotting factors in their blood.

**Research Study:**

The Principal Investigators of this study are Drs. Robert McMahon, Basel Hajjar and Jerry Bouquot. Drs. McMahon and Hajjar will be examining you and reviewing your dental and medical records at the Oral Surgery Group office in Merrillville, Indiana. Oral Pathologists at Indiana University Dental School (Drs. Larry Goldblatt and Susan Zunt) and the Maxillofacial Center (Dr. Jerry Bouquot) in Morgantown, West Virginia will authenticate your tissue diagnoses as well as participate in the enrollment of new patients. Dental specialists in Endodontics (Drs. William Adams and Ken Spolnik) from Indianapolis will offer their expertise in the conservation of teeth in areas of the jaw affected by the disease. Dr. Chares Glueck, Director of the Cholesterol, Metabolism and Thrombosis Center at MERCYHEALTH in Cincinnati, Ohio will oversee the results of the blood studies and, along with Dr. Ping Wang, will determine the statistical and clinical significance of your lab results, as to how they will affect you and your blood relatives.

If you choose to participate in this research study, the information we obtain will be strictly confidential. To determine if you are a candidate for this study, we will need to obtain a sample of your blood (30cc), so that it can be analyzed for the more common mutations affecting clotting factors that produce “super clots”.

Costs of the blood tests are very expensive, but will be *free* to you. Initials: \_\_\_\_

Attachment 7

Pt # \_\_\_\_\_

**To Participate in Research Study:**

1. Read the Patient Instruction Sheet. This form should be in the envelope mailed to you from Oral Surgery Group.
2. Sign authorization to release your medical/dental records (HIPAA Form).
3. After reviewing and signing this Consent Form for obtaining the necessary blood samples,

schedule a morning appointment for a blood draw at the Methodist Hospital Medical Laboratory (phone #: 219-738-5800), or a LabCorp medical laboratory closest to your

residence.

1. When you arrive at the medical laboratory, give the technologist the *Physician’s Order/Laboratory Instruction Sheet* *before* you have your blood draw. A small amount of blood is needed for testing (only 30cc). It will be analyzed for the presence of abnormal clotting factors. The laboratory cannot draw your blood without this order sheet.

When the results of the blood studies are made available, the doctor will call you and your Primary Care Physician and/or Oncologist to discuss the data. You and your doctors will be sent copies of the results of the blood tests.

**Your Rights and Obligations:**

Your participation in the research study is voluntary. If you decide to withdraw from the study, simply inform Dr. McMahon or Dr. Hajjar.

This Informed Consent is not intended to imply or guarantee that any treatment be given to you. We will notify you and your physician immediately and explain the clinical significance of any abnormal findings.

**Consent for Participation:**

I have read this INFORMED CONSENT and understand it to my satisfaction. I have had all of my questions answered so that I now understand it. I will submit to the drawing of my blood sample necessary for this research study.

You are invited/encouraged to ask questions at any time during the study. If you have any questions regarding the study, feel free to call Dr McMahon or Dr. Hajjar at (219) 757-5700.

You may be asked to have a consultation with some other specialist of your choice. Blood thinners will only be prescribed by your family medical doctor or oncologist.

While you have the right to discontinue treatment at any time, you must assume the responsibility for any events that occur as a result of discontinuing treatment.

Initials: \_\_\_\_

Attachment 7

Patient #: \_\_\_\_\_

**Consent for Participation:**

I have read this INFORMED CONSENT STATEMENT and understand it to my satisfaction. I have had all of my questions answered so that I understand it. I give permission for the release of dental and medical records as pertaining to osteonecrosis of my jaw and pertaining to osteoporosis.

You are invited to ask questions now or at any time later about this study. If you have any questions or want to report any study related problem, call Dr. McMahon or Dr. Hajjar at (219) 757-5700.

You should study this document carefully and ask about anything you don’t understand. Take this paper with you so that you can discuss it with your family doctor and dentist.

SIGNED:

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If someone other than Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ helped you to understand this statement, write the name and address here:

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ADMINISTERED BY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

WITNESSED BY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Initials: \_\_\_\_

Attachment 7