

**INFORMATION SHEET TO BE PART OF A RESEARCH STUDY**

**Title of Research:** Dental Implant Registry

**UAB IRB Protocol #:** IRB-300008804

**Principal Investigator:** Nicolaas C Geurs, DDS, MS

**Sponsor:** National Institutes of Health

<b>General Information</b>	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in this form.
<b>Purpose</b>	The purpose of this research study is to create a Dental Implant Registry to capture implant therapy that is provided by practitioners within the National Dental Practice-Based Research Network. To determine the therapies associated with the greatest amount of success and the least amount of complications.
<b>Duration &amp; Visits</b>	You will be in this study for at least 3 years. You will have an initial screening (baseline) and then once each year in year 1, year 2, and year 3. If funding is obtained, you will be asked to participate for additional data collection after year 3.
<b>Overview of Procedures</b>	If you are eligible and enroll in the study, you will be asked to complete a questionnaire regarding your health status, demographic information, and Oral Health Quality of Life at baseline visit. You will also complete an annual follow-up questionnaire. You will receive an email from <a href="mailto:CHR-NDPBRN-HUB@kpchr.org">CHR-NDPBRN-HUB@kpchr.org</a> with a link to the questionnaire.
<b>Risks</b>	The most common risks include the possible risk of loss of confidentiality. All data will be stored in a secure manner and accessible only by authorized study personnel. Electronic data will be encrypted.
<b>Benefits</b>	This research will not directly benefit you. However, this study may help us understand how to improve care for the implant in the future.
<b>Alternatives</b>	If you do not want to take part in the study, you do not have to be in the study. You can continue with your recovery as you normally would.

You are being asked to take part in a research study on dental implant therapy. The purpose of this research study is to create a Dental Implant Registry to capture implant therapy provided by practitioners within the National Dental Practice-Based Research Network. The aim is to determine the therapies associated with the greatest amount of success and the least amount of complications. This will allow better information to be shared with practitioners and patients regarding possible complications, which seem to be common occurrences within a significant number of implant restorations. This could give practitioners relevant information to assist in treatment decisions that would improve future patient outcomes. Your dentist is part of this research study. Approximately 200 practitioners from 6 regions in the United States will enroll approximately 800 patients with 2000 implants.

If you agree to join the study, you will be asked to complete a questionnaire regarding your health status, demographic information, and Oral Health Quality of Life at the baseline visit. Each questionnaire will take approximately 10 minutes to complete. You will be in the study for at least 3 years while you attend your regularly scheduled clinic visits. During annual follow up visits at year 1, 2, and 3 (-1 month - + 5 months) your

dentist will collect data on your oral health, peri-implant tissue health, the implant prosthesis, and routinely collected implant radiographs. At annual follow up visits, you will be asked to complete the annual follow-up questionnaire. If funding is obtained, you will be asked to participate for additional data collection after year 3. You will be paid \$25 per visit for completed questionnaires after each visit. If you complete the questionnaires at baseline, year 1, year 2, and year 3, then you will receive a total of \$100 (\$25 after each of four visits). You will be paid once each year if you participate each year. If you decide to stop being in the study for any reason, you will not receive any more payments. There is no cost to you for being in the study.

You will receive an email from [CHR-NDPBRN-HUB@kpchr.org](mailto:CHR-NDPBRN-HUB@kpchr.org) with a link to the questionnaire. Please check your spam folder. If you confirm the email is not in your spam folder, please email [CHR-NDPBRN-HUB@kpchr.org](mailto:CHR-NDPBRN-HUB@kpchr.org) with the subject line "Implant Registry".

When you fill out the questionnaire, you will be asked to provide your mailing address for payment purposes. You will also be asked to provide us with a name and contact information for an individual who can be contacted by your dental office, the research network's regional coordinator staff, or the National Coordinating Center. We will not release any of your information to the individual, beyond informing them that we are trying to contact you on behalf of the dental office.

This research will not directly benefit you. However, this study may help us understand how to improve care for the implant in the future.

Your participation in this research is strictly voluntary, and you are free to withdraw from this study at any time. Your choice to leave the study will not affect your dental care in any way. Although the study team will know your identity and contact information, this information will be kept confidential.

Your de-identified private information (private information with all identifiers removed) may be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

A possible risk of this study is loss of confidentiality. All data will be stored in a secure manner and accessible only by authorized study personnel. Electronic data will be encrypted for transmission to the National Coordinating Center, which is at the Kaiser Permanente Center for Health Research.

Potential risks to patients due to research participation are minimal. There will be no physical risk or discomfort for subjects who participate in the research.

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- National Institutes of Health (NIH)
- the Office for Human Research Protections (OHRP)
- National Dental Practice-Based Research Network (PBRN) Administrative and Resource Center (University of Alabama at Birmingham)
- National Coordinating Center (NCC) for the National Dental Practice-Based Research Network (Kaiser Permanente Center for Health Research)

The information from the research may be published for scientific purposes; however, your identity will not be given out in those publications.

This research is covered by a Certificate of Confidentiality from the NIH. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect or harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Whether or not you take part in this study is your choice. Your participation in this study is voluntary, so you can choose to be in this study or not. If you decide not to be in the study, it will not affect your care today or in the future; participating in the study may not necessarily directly benefit you. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution or dental practice. Contact the study doctor if you want to withdraw from the study.

There will be no cost to you for taking part in this study.

You will be paid \$25 per visit for completed questionnaires after each annual visit. If you decide to stop being in the study for any reason, you will not receive any more payments.

If you have any questions, concerns, or complaints about the research please contact the Principal Investigator, Dr. Nicolaas Geurs, at 205-934-4506. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Thank you for your participation in the National Dental PBRN!

**University of Alabama at Birmingham (UAB)**  
**AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION**  
**FOR RESEARCH**

**What is the purpose of this form?** You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

**Participant Name:** \_\_\_\_\_  
**Research Protocol:** A Dental Implant Registry of Treatment Outcomes Of Implant Therapy By Practitioners In The National Dental Practice-Based Research Network (Dental Implant Registry)

**UAB IRB Protocol Number:** IRB-300008804  
**Principal Investigator:** Dr. Gregg Gilbert

**Sponsor:** National Institutes of Health

**What health information do the researchers want to use?** All dental or medical information and personal identifiers collected for use in the research protocol.

**Why do the researchers want my health information?** The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

**Who will disclose, use and/or receive my health information?** The personnel working on the research protocol (whether at UAB or elsewhere); other operating units of UAB (e.g., Health Services Foundation, UAB Health System, Children's Hospital of Alabama) and the Jefferson County Department of Public Health, as necessary for their operations; the UAB Institutional Review Board (IRB) and its staff; the sponsor of the research and its employees; and outside regulatory agencies.

**How will my health information be protected once it is given to others?** Your health information will be given to UAB personnel associated with the study. All information is stored in a secure manner. It is possible the study sponsor (the National Institutes of Health) would also request this information. If we forward the information to the study sponsor, or if we were required by court order to provide any information to an entity that is not required to follow federal privacy laws, we cannot assure that the information will remain protected.

**How long will this Authorization last?** Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

**Can I cancel the Authorization?** You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the personnel will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

**Can I see my health information?** You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: \_\_\_\_\_ Date: \_\_\_\_\_

or participant's legally authorized representative: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name of participant's representative: \_\_\_\_\_

Relationship to the participant: \_\_\_\_\_

# Patient Demographic Form

1. What is your gender? Female   
Male   
Nonbinary   
Prefer not to answer
2. What is your date of birth? \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_
3. Are you of Hispanic or Latino origin? Yes 1  
No 0  
Prefer not to answer 2
4. What racial categories best describe you? American Indian or Alaska Native 1  
*(Check all that apply)* Asian 1  
Native Hawaiian or Other Pacific Islander 1  
Black or African-American 1  
White or Caucasian 1  
Prefer not to answer 1
5. What type of dental insurance do you have?  
No dental insurance 1  
Private insurance (e.g. employer sponsored, commercial, HMO, etc.) 2  
Public/government insurance (Medicaid, military or veterans benefit, etc.) 3  
Private and Public/Government (e.g., private plus Medicare) 4  
Other 5  
I don't know 6  
Prefer not to answer 7
6. Indicate your highest level of formal education Less than high school diploma 1  
High school diploma or GED 2  
Some college/Associate degree 3  
Bachelor's degree 4  
Graduate degree 5  
Prefer not to answer 6
7. How would you describe the neighborhood where you live? Urban 1  
Suburban 2  
Rural 3
8. What is the ZIP Code where you live? \_\_\_\_\_
9. Including you, how many people live in your household?
10. What is your family's current annual household income from all sources? Up-to (less than or equal to) \$25,000 1  
\$25,001-\$50,000 2  
\$50,001-\$100,000 3  
Over \$100,000 4  
Prefer not to answer 5

# Baseline Patient Characteristics

1. In the last 12 months, have you seen a physician for routine annual physical examinations?

Yes

No

2. Have you ever been diagnosed with Diabetes Mellitus?

Yes

No

*If yes, which type?* Type I

Type II

Gestational Diabetes

*If yes, What year was your diabetes first diagnosed?* Year \_\_\_\_\_

*If yes, What was your last HbA1c? Drop down box continuous scale* Choose an item.

Other: \_\_\_\_\_

Unknown

*If unknown, skip this question:* To your best estimate, on what date was your last HBA1c? : \_\_\_\_/\_\_\_\_/\_\_\_\_

\_\_\_\_

3. Do you have any drug or environmental allergies?

Yes

No

*If yes, check all that apply:*

Food

Seasonal

Penicillin

Drugs (other than Penicillin)

Metals

Other:

*If food checked: Enter your food allergies* \_\_\_\_\_

*If drugs checked: Enter your drug allergies* \_\_\_\_\_

## Baseline Patient Characteristics

4. Have you ever been diagnosed with any of the following health conditions? *Check all that apply:*

- High blood pressure
- Heart attack
- Abnormal bleeding condition
- Rheumatoid Arthritis
- Autoimmune Diseases
- Chronic/ Recurring Sinus Problems
- Depression
- Liver Disease
- Joint Replacement
- Organ Transplants
- Osteoporosis
- Parkinson's Disease
- Serious/Frequent Headaches
- Cancer
- Other
- None

*If cancer checked:* What type of cancer? Choose an item.

*If cancer checked* Did you receive chemotherapy or radiation treatment? (mark all that apply)

Chemotherapy

Radiation Treatment

*If yes to radiation treatment:* What area of the body was radiated? \_\_\_\_\_

5. Are you currently taking any medications? (Check all medications that you take: this include OTC, herbs, vitamins, and supplements)

None

**Blood pressure medications** (e.g. Privilil, Norvasc, hydrochlorothiazide, atenolol, Toprol, etc)

**Anti-depression/anxiety** (e.g. Lexapro, Prozac, Paxil, Cymbalta, Effexor)

**Antihistamine or allergy medications** (e.g. Claritin, Flonase, Allegra)

**Thyroid-related meds** (e.g. Synthroid)

**Prescribed pain medications** (e.g. oxycodone, hydrocodone, codeine, Fentanyl)

**Over the counter pain medications** (e.g. Tylenol, Ibuprofen, Advil, Aleve)

**Diabetes medications** (e.g. metformin, insulin, etc)

**Acid reflux or GERD meds** (e.g. esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec)

**Steroids** (e.g. Prednisolone, Betamethasone)

**Rheumatoid arthritis meds** (e.g. Humira (Pro) Generic name: adalimumab; Enbrel (Pro) Generic name: etanercept; Remicade (Pro) Generic name: infliximab; Simponi (Pro) Generic name: golimumab)

**Sleep medications** (e.g. Halcion, Lunesta, Ambien)

**Antibiotics** (e.g. amoxicillin, metronidazole, tetracyclines)

**Osteoporosis medications** (e.g. Alendronate Sodium or Alendronate Sodium plus Vitamin D3 (Fosamax<sup>®</sup>, Fosamax Plus D and Binosto<sup>®</sup>) Ibandronate Sodium (Boniva<sup>®</sup>) Risedronate Sodium (Actonel<sup>®</sup> and Atelvia<sup>™</sup>)

Zoledronic Acid (Reclast<sup>®</sup>) Denosuma (Prolia<sup>®</sup>) Calcitonin-Salmon (Fortical<sup>®</sup> and Miacalcin<sup>®</sup>)

**Other:**

## Baseline Patient Characteristics

6. Have you ever been told by a dentist that you have a dry mouth or Xerostomia? Yes   
No
7. Do you frequently have difficulty swallowing food? Yes   
No
8. Do you frequently feel dry mouth during meals? Yes   
No
9. Do you frequently have a burning sensation on your tongue? Yes   
No
10. Have you smoked at least 100 cigarettes in your entire life? Yes   
No   
Don't know   
Prefer not to answer

*If yes:* How long has it been since you started smoking cigarettes? If today, enter 1 day. \_\_\_ Days  
\_\_\_ Months  
\_\_\_ Years

On average, how many cigarettes did you smoke each day **before** the study implant placement?(Note: there are 20 cigarettes per pack) \_\_\_\_\_

If you have smoked **since** your implant placement or are currently smoking, on average, how many cigarettes do you smoke each day? (Note: there are 20 cigarettes per pack) \_\_\_\_\_

11. Have you ever used smokeless tobacco regularly? Yes   
No   
Don't know   
Prefer not to answer

*If yes:* How long has it been since you started using smokeless tobacco? (*If today, enter 1 day.*) \_\_\_ Days  
\_\_\_ Months  
\_\_\_ Years

On average, how many times did you use smokeless tobacco each day **before** implant placement? \_\_\_\_\_



## Baseline Patient Characteristics

If you have used smokeless tobacco **since** your implant placement or are currently using, on average, how many times do you use smokeless tobacco each day? (If you have not, enter 0.) \_\_\_\_\_

12. Have you ever smoked cigars, cigarillos and/or filtered cigars?

- Yes   
No   
Don't know   
Prefer not to answer

*If yes:* How long has it been since you started smoking cigars, cigarillos, and/or filtered cigars? If today, enter 1 day. \_\_\_ Days  
\_\_\_ Months  
\_\_\_ Years

On average, how many cigars, cigarillos, and/or filtered cigars did you smoke each day **before** implant placement? \_\_\_\_\_

If you have smoked cigars, cigarillos, and/or filtered cigars **since** your implant date or are currently smoking, on average, how many do you smoke each day? (If you have not, enter 0.) \_\_\_\_\_

## Baseline Patient Characteristics

13. Have you ever used an electronic nicotine product (E-cigarettes, vaping) fairly regularly?

Yes

No

Don't know

Prefer not to answer

*If yes:* How long has it been since you last used an electronic nicotine product? If today, enter 1 day. \_\_\_\_

Days

\_\_\_\_ Months

\_\_\_\_ Years

On average, in a typical month, how many days did you use an electronic nicotine product **before** implant placement? \_\_\_\_

If you have used an electronic nicotine product **since** your implant date or are currently using, on average in a typical month, how many days did you use an electronic nicotine product? If you have not, enter 0. \_\_\_\_\_

## Patient Contact

**PPTID**

1

Please fill in the below contact and back-up contact information. This information is used to keep in touch with you and to process your study payment.

Name:	First: <input type="text"/>	Middle: <input type="text"/>
	Last: <input type="text"/>	Suffix: <input type="text"/>
Home address:	Street: <input type="text"/>	
	City: <input type="text"/>	
	State: <input type="text"/>	Zip: <input type="text"/>
Primary phone number:	<input type="text"/>	
Phone type:	<input type="radio"/> Cell <input type="radio"/> Home <input type="radio"/> Work <input type="radio"/> Other	
Do you want to receive text messages at this number? (standard rates may apply)	<input type="radio"/> Yes <input type="radio"/> No	
Secondary phone number: (optional)	<input type="text" value="(999) 999-9999"/>	
Phone type:	<input type="radio"/> Cell <input type="radio"/> Home <input type="radio"/> Work <input type="radio"/> Other	
Do you want to receive text messages at this number? (standard rates may apply)	<input type="radio"/> Yes <input type="radio"/> No	
What is the best method to contact you?	<input type="radio"/> Phone call <input type="radio"/> Text (standard rates may apply) <input type="radio"/> Email <input type="radio"/> No preference	

## Backup Contact

Please provide contact information of a friend or family member who would know how to contact you. Please let them know that you are in a study and that we will contact them ONLY if we cannot reach you. We will not reveal the topic of the study or any information about you related to the study.

Contact's first and last name

\* must provide value

What is this person's relationship to you?

\* must provide value

What information would you like to provide for us to contact your friend or family member?  
(Check all that apply)

- Email address
- Phone number

[Email and phone number data sections \(below\) show when these boxes are marked](#)

\* must provide value

Contact's email address

\* must provide value

Contact's phone number

\* must provide value

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**Form Status**

**Complete?**

Incomplete ▼

## Oral Health Quality of Life

<i>Please answer the following questions in relation to your dental health, function and esthetics prior to the implant therapy.</i>	<i>Never</i>	<i>Sometimes</i>	<i>Always</i>	<i>Not sure</i>
How often do you limit the kind or amount of food you eat because of problems with your teeth or your current prosthesis?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often do you have trouble biting or chewing any food?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often do you have difficulty in speaking due to problems with your teeth?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often do you have pain while chewing/biting food?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often do you have pain/discomfort while brushing/flossing?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often do you have to take medications because of pain due to problems with your teeth?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often do you limit contact with people due to problems with your teeth?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often are you happy with the looks of your teeth?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often do you feel uncomfortable eating in front of people due to problems with your teeth?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often do you feel satisfied and happy with your teeth?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

# Patient Annual Follow Up

1. Have you been diagnosed with Diabetes Mellitus since your last study visit?

Yes

No

*If yes, which type? Type I*

Type II

Gestational Diabetes

*If yes, When was it diagnosed?* \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

*If yes, What was your last HbA1c? Choose an item.*

Other:

Unknown

2. Are there any changes in your health since your last study visit?

Yes

No

*If yes: What new conditions have been diagnosed? Check all that apply:*

High blood pressure

Heart attack

Abnormal bleeding condition

Rheumatoid Arthritis

Autoimmune Diseases

Chronic/ Recurring Sinus Problems

Depression

Liver Disease

Joint Replacement

Organ Transplants

Osteoporosis

Parkinson's Disease

# Patient Annual Follow Up

Serious/Frequent Headaches

Other:

Cancer

*If cancer:* What type of cancer? Choose an item.

*If cancer:* Other:

*If cancer:* Did you receive chemotherapy or radiation treatment? (mark all that apply)

Chemotherapy

Radiation Treatment

*If cancer and radiation treatment:* What area of the body was radiated? \_\_\_\_\_

3. Are you currently taking any medications? (Check all medications that you take: this includes OTC, herbs, vitamins, and supplements):

None

**Blood pressure medications** (e.g. Privilil, Norvasc, hydrochlorothiazide, atenolol, Toprol etc)

**Anti-depression/anxiety** (e.g. Lexapro, Prozac, Paxil, Cymbalta, Effexor)

**Antihistamine Or allergy medications** (e.g. Claritin, Flonase, Allegra)

**Thyroid-related meds** (e.g. Synthroid)

**Prescribed pain medications** (e.g. oxycodone, hydrocodone, codeine, Fentanyl)

**Over the counter pain medications** (e.g. Tylenol, Ibuprofen, Advil, Aleve)

**Diabetes medications** (e.g. metformin, insulin etc)

**Acid reflux or GERD meds** (e.g. esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec))

**Steroids** (e.g. Prednisolone, Betamethasone)

**Rheumatoid arthritis meds** (e.g. Humira (Pro) Generic name: adalimumab (Enbrel (Pro) Generic name: etanercept; Remicade (Pro) Generic name: infliximab; Simponi (Pro) Generic name: golimumab)

**Sleep medications** (e.g. Halcion, Lunesta, Ambien)

# Patient Annual Follow Up

**Antibiotics** (e.g. amoxicillin, metronidazole, tetracyclines)

**Osteoporosis medications** (e.g. Alendronate Sodium or Alendronate Sodium plus Vitamin D3 (Fosamax®, Fosamax Plus D and Binosto®) Ibandronate Sodium (Boniva®) Risedronate Sodium (Actonel® and Atelvia™) Zoledronic Acid (Reclast®) Denosuma (Prolia®) Calcitonin-Salmon (Fortical® and Miacalcin®)

**Other:**

4. Have you ever been told by a dentist that you have a dry mouth or Xerostomia?

Yes

No

5. Do you frequently have difficulty swallowing food?

Yes

No

6. Do you feel dry mouth during meals?

Yes

No

7. Do you frequently have a burning sensation on your tongue?

Yes

No

8. Have you used nicotine products since your last study visit?

Yes

No



# Patient Annual Follow Up

If yes to #8.

8a. Which nicotine products have you used since your last study visit?

(Check all that apply)

- Cigarettes
- Smokeless tobacco
- Cigars
- An electronic nicotine product

Show only if cigarettes is checked in #8:

8b. How long has it been since your last cigarette?

If today, enter 1 day. \_\_\_ Days

\_\_\_ Months

\_\_\_ Years

8c. On average, how many cigarettes do or did you smoke each day? (Note: there are 20 cigarettes per pack) \_\_\_\_\_

Show only if smokeless tobacco is checked in #8:

8d. How long has it been since you last used smokeless tobacco?

If today, enter 1 day. \_\_\_ Days

\_\_\_ Months

\_\_\_ Years

8e. On average, how many times do or did you use smokeless tobacco each day? . \_\_\_\_\_

Show only if cigar is checked in #8:

8f. How long has it been since you last smoked a cigar, cigarette and/or filtered cigar?

If today, enter 1 day. \_\_\_ Days

\_\_\_ Months

\_\_\_ Years

8g. On average, how many cigars cigar, cigarettes and/or filtered cigars do or did you smoke each day? \_\_\_\_\_

Show only if an electronic nicotine product is checked in #9:

# Patient Annual Follow Up

8h. How long has it been since your last usage of an electronic nicotine product? If today, enter 1 day.  
 \_\_\_ Days

\_\_\_ Months

\_\_\_ Years

8i., On average in a typical month, how many days do or did you use e-nicotine?. \_\_\_\_\_

**Please answer the following questions in relation to the dental implant/implants and implant supported prosthesis.**

<i>Questions</i>	<i>Never</i>	<i>Sometimes</i>	<i>Always</i>	<i>Not sure</i>
<b>9 Since your last study visit...</b>				
How often did you limit the kind or amount of food you ate because of problems with your implant and implant supported prosthesis site?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often did you have trouble biting or chewing any food at the implant and implant supported prosthesis site?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often did you have difficulty in speaking due to problem at the implant and implant supported prosthesis site?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often did you have pain while chewing/biting food at the implant and implant supported prosthesis site?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often did you have pain/discomfort while brushing/flossing at the implant site?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often did you have to take medications because of pain at the implant site?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Patient Annual Follow Up

How often did you limit contact with people due to problem with your implant and/or implant supported prosthesis?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often were you happy with the looks of the implant supported prosthesis?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often did you feel uncomfortable eating in front of people due to problems with your implant and/or implant supported prosthesis?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often did you feel satisfied and happy with the implant and implant supported prosthesis?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>