INFORMATION NOTE

Introduction
An experimental study entitled “A possible correlation between periodontal disease and systemic diseases: a clinical study” is being planned at the Department of Medicine and Surgery of the University of Milan Bicocca.

To carry out this research, we need the collaboration and availability of people who, like you, meet the scientific requirements suitable for the evaluation that will be performed. However, before you make the decision to accept or refuse to participate, we ask you to read these pages carefully, taking all the time you need, and to ask us for clarifications if you do not understand or need further clarifications. Furthermore, if you wish, before deciding, you can ask your family members or a trusted doctor for an opinion.

Purpose of the Research
The aim of this work is to verify the possible relationship between some systemic diseases and periodontal disease.

What your participation in the Research entails
If you agree to participate in this Research, you will be asked to sign this Informed Consent form.
The research will last a maximum of 3 months.
Participation in this procedure does not entail any financial burden for you, nor does it provide for any compensation.

What are the benefits that you will receive by participating in the Research
The procedures that you will be subjected to during the study are commonly used. There will be no particular benefits for you deriving from participation in the research.

What are the risks deriving from participation in the Research
The procedure does not involve risks.

Insurance Coverage
Given the nature of the proposed study, no additional insurance policies are foreseen in addition to those already foreseen for normal clinical and research practice.

Confidentiality of personal data
Pursuant to Legislative Decree No. 196/03 (Articles 7 and 13) relating to the protection of the person for the processing of personal data, we inform you that your personal data will be collected and archived in an appropriate manner and will be used exclusively for scientific research purposes. Data archiving and processing procedures will be implemented that will prevent people outside our research group from being able to associate your name with the data themselves.

You have the right, if you wish, to know what information will be archived and how.
Access to such data will be permitted only to authorised personnel. The Ethics Committee of this Department may inspect the archive without however being able to trace your personal identity.

The results of the Research in which you will participate may be published, but your identity will remain secret. In particular, your data will not be disclosed to the researchers, who will only know the date of sampling. This is an experimental study from which the researchers involved will not derive any direct benefit. By signing the Informed Consent form, you authorise access to the experimental data concerning you as set out above.

Information about the Results
If you request it, at the end of the research, the results in general and in particular those concerning you may be communicated to you.

Further information
For any information, you may contact:

prof. _____ cell. _____

The research protocol that has been proposed to you has been drawn up in accordance with the European Union Good Clinical Practice Standards and the current revision of the Declaration of Helsinki and has been approved by the Ethics Committee competent for this Department, which works to ensure the protection of the rights, integrity and well-being of the subjects involved in the trials.

If you join the project, you may request further information on the research and the progress achieved at any time, and you will be promptly informed if information becomes available that may influence your willingness to continue to join the project.

You will also be able to access the documentation relating to the research in question and the opinion expressed on it by the Ethics Committee.

Furthermore,

☐ authorize ☐ not authorize

researchers to contact me or my family members in the future for participation in further studies.

Having acquired the information on the processing of personal and sensitive data, and hereby,

☐ authorize ☐ not authorize

to the processing of my personal data, including sensitive data, for the purposes indicated in the Information Note.

Date _____ Signature _____

INFORMED CONSENT FORM

I, the undersigned _____

Born in: _____ on: _____

I declare that I have received from Dr. _____ comprehensive explanations regarding the request to participate in the research in question, as reported in the attached information note, a copy of which was delivered to me sufficiently in advance (date_____).

I also declare that I have been able to discuss these explanations, to ask all the questions that I deemed necessary and to have received satisfactory answers, as well as to have had the opportunity to inquire about the details of the research from a person I trust.

I confirm that I have freely chosen to participate in this research, having fully understood the meaning of the request and having understood the risks and benefits that are involved, knowing that, at any time, I can:
 ask the personnel responsible for this research for further information;
 communicate any changes of opinion regarding what has been declared;
 to withdraw spontaneously at any time from the research without having to provide justification;
 for further information I can contact the Scientific Director of the research or a person designated by him.

I have also been informed of my right to have free access to the documentation relating (insurance, clinical-scientific) to the research and to the evaluation expressed by the Ethics Committee.

 I agree I do not agree:

Date _____ Signature of the patient_____

Date_____ Signature of the doctor _____

[In case the patient cannot read and/or sign]

I, the undersigned:_____
testify that Doctor_____
has thoroughly explained to Mr._____
the characteristics of the research in question, as reported in the attached information note, and that the latter, having had the opportunity to ask all the questions he deemed necessary, has freely agreed to participate in the research.

Date_____ Signature of the independent witness_____

INFORMATION AND CONSENT TO THE PROCESSING OF PERSONAL DATA

Pursuant to the “Guidelines for the processing of personal data in the context of clinical trials of medicinal products” adopted by the Guarantor for the protection of personal data with Resolution no. 52 of 24 July 2008 (G.U. no. 190 of 14 August 2008)

Data controllers and related purposes

The Department of Medicine and Surgery of the University of Milan Bicocca where the research described to you is being carried out, in accordance with the responsibilities established by the rules of good clinical practice (d.l. 211/2003), will process your personal data, in particular health data and, only to the extent that they are indispensable in relation to the objective of the research, other data relating to your origin and your lifestyle, exclusively for the purpose of carrying out the research and in a strictly anonymous manner.

To this end, the data indicated will be collected by the personnel involved in the research, including:
Prof. _____

The processing of personal data relating to age and sex is essential to the conduct of the research: refusal to provide them will not allow you to participate.

Nature of the data
The researcher who will follow you in this research will identify you with a code; the data concerning you collected during the research, with the exception of your name, will be recorded, processed and stored together with this code, your date of birth, and sex. Only authorized subjects will be able to connect this code to your name.

Method of processing
The data, processed using electronic tools, will be disclosed only in a strictly anonymous form, for example through scientific publications, statistics and scientific conferences. Your participation in the research implies that, in accordance with the regulations on clinical trials of medicinal products, the Institute's staff who monitor and verify the research, the Ethics Committee and the Italian and foreign health authorities will be able to know the data concerning you, also contained in your original clinical documentation, in ways that guarantee the confidentiality of your identity.

Exercise of rights
You may exercise the rights referred to in art. 7 of the Code (e.g. access your personal data, integrate them, update them, rectify them, oppose their processing for legitimate reasons, etc.).
You may interrupt your participation in the research at any time and without providing any justification: in this case, the biological samples related to you will be destroyed. Furthermore, no further data concerning you will be collected, without prejudice to the use of any data already collected to determine, without altering them, the results of the research.

Consent
By signing this form, I consent to the processing of my personal data and their transfer outside the European Union (to be inserted if carried out specifying the identification details of the

recipients) for the purposes of the research within the limits and with the methods indicated in the information provided to me with this document.

Name and Surname of the interested party (in capital letters) _____

Signature of the interested party _____

Date _____

Date _____ Signature of the proposer _____

(Signature of a member of the Department) _____