| **Information about the study** *(Please be detailed, if required additional documents can be attached as an appendix)* | |
|---|---|
| **Study title** | |
| **Study objectives**<br>*(Including hypothesis)* | |
| **Importance of Results**<br>*(Please detail the scientific, practical or clinical relevance of the findings of the study)* | |
| **Study design**<br>*(A brief summary of major study design features i.e. in vitro, animal or clinical study, follow up times and study end point)* | |
| **Study population**<br>*(For clinical/animal study describe target population, indication studied and inclusion/ exclusion criteria's)* | |
| **Number of planned patients/animals**<br>*(If multi-centre study also describe the distribution per study site)* | |
| **Study centre(s)**<br>*(The site(s) were the majority of the research will be conducted)* | |
| **Estimated Study period**<br>*(MMM/YYYY)* | to |
| **Milestones**<br>*(Detail the different milestones / important events in the study and at which date you estimate them to occur. Examples of milestones are first patient included, all patients included, last follow up conducted or end of an experimental serie)* | |

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| **Investigational product/ comparator**<br>*(State the devices/ products that will be investigated/ used and for comparative studies also the comparator/s)* | |
| **Outcome variables**<br>*(Describe what outcomes will be measured by the study i.e. what will be measured and how is it related to the results)* | |
| **Materials and methods**<br>*(Detail the procedures, methods and measurements that will be conducted within the study)* | |

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| **Statistical methods**<br>*(Detail the statistical tests, populations for comparison, sample size, intention to treat, per-protocol and any interim analyses)* | |

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| **Publications & presentations**<br>*(Describe plans for publication or public presentations of results also give examples of journals to submit to or conferences/ meetings to attend)* | |
| **Research experience as principal investigator**<br>*(If applicable, please describe your previous research experience and number of published articles in international peer-reviewed journals with you as principal investigator)* | |
| **Dentsply Sirona Implants contact person** *(if applicable)* | *Please specify name, email-address/ phone no.:* |
| | ☐ Local contact |
| | ☐ Contact person who is involved in this application |

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| **Total study cost**<br>*(Estimate a reasonable total budget for the study. Detail costs for materials, products, staff, procedures, measurements, ethical approvals etc.)* | |
| **Further support**<br>*(Did you or do you plan to request further support by any other person/ institution/ company?)* | ☐ No<br>☐ Yes<br>*If yes, please specify type and amount of funding as well as the name f the person/ institution/ company you did ask or plan to ask for support in terms of this study.* |

| **Requested Support from Dentsply Sirona Implants** | |
|---|---|
| **Support requested**<br>*(Products and funding. For funding detail the amount to be covered by requested support. For products detail these in the next section)* | |

| **Details of products requested** *(Only Dentsply Sirona Implants devices)* | | |
|---|---|---|
| **Product** | **Ref. No.** | **Quantity** |
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| **Products will be distributed to the below contact person and address:** | | |

| **Applicant information** | |
|---|---|
| Principal Investigator<br>*(Title and name)*<br>Name of Institution/Clinic<br><br>Address<br><br><br>Phone number<br>E-mail address | |
| Please list all investigators who will be involved in your study<br>*(Please specify name, title, anticipated function, instiution/clinic)* | |
| Please indicate the reason for your interest in collaboration with Dentsply Sirona Implants | |

1. The investigator, or the Investigator's responsible Medical Institution, will act as the Sponsor for the IIS and will fulfill all the obligations of being a Sponsor.
2. The IIS will be conducted in accordance with this study proposal, and ISO 14155 or respective FDA requirements (if conducted in North America), as well as with all further regulatory requirements and local laws.
3. The Investigator will ensure that the IIS is approved by the Institution's IEC/IRB and, if appropriate, by the relevant regulatory authorities.
4. Major changes in study design and support requests, which are proposed after decision, might require a new application to be submitted.
5. When submitting the Study proposal, applicant information, such as name and title of the Investigator and the persons who will be involved in the study will be processed and stored in a central database, used by DENTSPLY IH AB or any of its affiliates ("DENTSPLY"), for the purpose of documenting DENTSPLY's decision on whether to support the proposed study. You do not have any obligation to submit this information to us. However, the processing is based on a proposed contractual relation; in so that we cannot proceed with your application should you not agree with us processing the above listed personal data. The personal data will furthermore be processed and stored in order to follow up on the studies that have been submitted as well as for statistical purposes. Depending on where the study will be conducted, the personal data may be transferred to countries outside of the European Economic Area (EEA), where the local laws may not grant the same level of data protection as is guaranteed by the EU Data Protection Directive (or similar legislation). The data subjects have the right to once a year and for free, request a copy of the information that DENTSPLY holds about them and to, at any time, request any inaccuracies in this information to be corrected, or that the information is deleted. In such a case, the data subject should use a written request and sign it personally and send it DENTSPLY IH AB, Att: The Data Privacy Officer, Box 14, 431 21 Mölndal, Sweden.

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| **Investigator** | ☐ I accept the conditions listed above.<br>☐ I declare that all given information is correct. |

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| *Date (DD/MMM/YYYY)* | *Name (Principal Investigator)* | *Signature (omit if submitted digitally)* |