KING KHALID UNIVERSITY
COLLEGE OF DENTISTRY
SCIENTIFIC RESEARCH COMMITTEE

OFFICIAL USE ONLY

REGISTRATION NUMBER: SRC/ETH/20 / REGISTRATION DATE:

APPLICATION FOR ETHICAL CLEARANCE: (CLINICAL TRIALS)

Research Title

Research Type

Staff research: ☐ Internship research: ☐

Student research: ☐ Funded research: ☐

Principal Investigator:

Name:
Position :
Tel no:
Email:

Co-Investigators

1.
2.
3.
4.

Research Details

Research site:

Multi-site study: Yes: ☐ No: ☐

Proposed start date:

Anticipated study duration:

Participant detail:
Male: Female: Total:

Age range: years to

Method of participant selection:

N/A

Are there any perceived potential risks for participants/ researchers? Yes: ☐ No: ☐
If Yes Explain:

Participant Check List

Will informed consent be obtained? (attach the copy)	Yes ☐	No ☐
Will questionnaire be used? (attach the copy)	Yes ☐	No ☐
Relationship between investigator and participant:		
Does the research include procedures on Under-age subjects?	Yes ☐	No ☐
Does the study involve Vulnerable groups? (Mentally/physically challenged…)	Yes ☐	No ☐
Is there any financial /other inducement:	Yes ☐	No ☐
Are any participants or research related work from outside KSA?	Yes ☐	No ☐

Data Collection & Handling

Form of data collection;
Identified: ☐ Potentially identifiable: ☐
De-identified: ☐

Data storage:
Identified: ☐ Potentially identifiable: ☐
De-identified: ☐

Is collected data secured? Yes : ☐ No: ☐

Are the participants identifiable in publication /output ?: Yes : ☐ No: ☐

Action of SRC-COD

Signature of Chairperson-SRC-COD

1. Mandatory for all investigations involving human participants with Clinical trials.
2. Please submit additional documents if required /asked to confirm the ethical practice in research activity and data handling.

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Fill appropriate sections applicable for your research

Administration Of Substance/ Drugs

Name of substance:

Dosage per administration:

Frequency of administration:

Total amount of administration:

Is your study a non-interventional trial?
Yes: ☐ No: ☐
Please register with Saudi food and drug agency (**MDCI@sfda.gov.sa**)

Is your study a Post-Authorisation safety trial?
Yes: ☐ No: ☐
Please register with Saudi food and drug agency (**MDCI@sfda.gov.sa**)

Anticipated effects:

Bodily Tissue Collection

The bodily tissue collection is:
Prospective : ☐ Retrospective: ☑

What tissue/ fluid :

Frequency and volume

Method of storing /disposing

Who will collect and expertise in doing so:

The collection of biological material is for :
Clinical care : ☐ Research purpose: ☑

Radioactive Material

Exposure to Radioactive material: Yes ☐ No ☐
Therapeutic : ☐ Diagnostic: ☐

Does the trial involve additional radiation exposure? Yes: ☐ No: ☐

State the associated risk:

Explain about clinical monitoring and safety measures of the participants:

Qualification and competence of Principal Investigator :

Medical Devices

This study on medical device is:
Trial investigating : ☐ Evaluating : ☐

Name of the Instrument/ Device:

Is the instrument approved for safety standards? Provide details:

Is the study within the terms of its safety standards or to obtain the safety standard certificate? Provide explanation:
Please register with Saudi food and drug agency (**MDCI@sfda.gov.sa**)

I declare that the above project has been developed and will be conducted in accordance with relevant SRC-COD standards, policies, and codes of practice including any standard or special condition for ongoing ethics clearance. In case, there will be any changes in the procedures for obtaining the subjects, or if there will be some physical or emotional harm to the subjects, I shall report these to the SRC-COD.

Signature of Principal Investigator(Including on behalf of all Co-Investigators)

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