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Kingdom of Saudi Arabia
Ibn Sina National College for Medical Studies, P.O. 31906, Jeddah- 21418. C.R.: 4030144057

المملكة العربية السعودية
كلية ابن سينا الاهلية للعلوم الطبية
ص ب: 31906 .p.o ، جدة:21418
س.ت: 4030144057

"IBN S1NA NATIONAL COLLEGE–RESEARCH CENTE"

(ISNC–RC)

Application for approval/Registration of research proposal (with/without fund)

General instruction and guidance to the user

1. Please refer Section H for the form **FILLING INSTRUCTIONS**
2. All are mandatory fields (Section A-G) to he filled, wherever not applicable please indicate as "NA".
3. Incomplete application (this form completely and correctly filled-in with all required attachments signed confirmation) shall be **automatically un-submitted**.
4. It is the responsibility of the applicant to fill-in and submit accurate information.
5. Soft copy of the completed application is to be submitted only through ISNC-RC's project submission (E-file sharing) system and signed hard copies to be submitted to the office of ISNC¬RC
6. Only upon successful completion of initial technical review, the application shall be processed further (i.e. peer review, ethics committee approval, registration of the research project etc.).
7. This application is meant for approval and registration of research project by ISNC-RC (intellectual property). Therefore unauthorized **(without signature / and stamp from the office ISNC-RC)** submission/distribution of this filled-in application in any form outside ISNC **is strictly prohibited.**
8. In the event of any difficulty faced while completing this application please do not hesitate to contact your respective Program Research Team coordinator/ISNC-RC.

Section A: Applicant Details

A.1	Principal investigator	
	Name	AMIT VANKA
	ID number (Employee ID/Student ID)	
	Program	DENTISTRY
	Department	PREVENTIVE DENTAL SCIENCES
	Designation of principle investigator	ASSOCIATE PROF.
	Contact email	amitvanka@rediffmail.com
	Google Scholar ID	
	Research gate ID	
	ORCHID Number	
	Contact No.	00966597697765

A.2	**Coinvestigator/s (research team)**					
	No.	**Name**	Participate **type**	Program/. Department	Designation	**Email**
	1	Mohammed John	Research Assistant 1	Dentistry	Intern	
	2	Hani at zahrani	Research Assistant 2	Dentistry	Intern	
	3	Hamza at Wagdani	Research Assistant 3	Dentistry	Intern	
	4	Ahmed Al Sharief	Research Assistant 4	Dentistry	Intern	
	5	Nanman	Research Assistant 5	Dentistry	Intern	

*Undergraduate student at Ibn Sina National College for Medical Studies

Section B: Details of Research Project

B.1	**Project overview**	
B.1.1	title	Pulse oximeter: a diagnostic tool to assess pulp vitality
B.1.2	Background and rationale of the project (maximum up to 350 words	Pulp vitality is measured by various methods broadly classified into: pulp sensibility measurements and pulp vitality measurements. Pulp sensibility measurements such as the thermal tests and electric pulp tests measure the nerve stimulation and as such may suffer from inherent drawbacks of eliciting false positives and false negatives. Vitality may therefore be considered to be a measure of the blood circulation in the pulp. Pulse oximeter is a device routinely used in medical field to measure the oxygen saturation of peripheral blood circulation. Recent studies have reported on the possibility of utilizing this device to measure pulp vitality. Some of the concerns are related to the accurate placement of the device to adapt to the contours of the tooth. It is noteworthy to mention that few, if any commercial brands have been developed to exclusively measure the oxygen saturation from the tooth. In this context, the current study is to be undertaken to develop a pulse oximeter capable of consistently recording the oxygen saturation and hence the vitality of the pulp. Literature supports evidence that young permanent teeth may have a better chance of recovering from a traumatic injury, probably due to the wide foramen providing an enhanced blood supply. The study thus also aimed to compare the blood circulation between young permanent teeth and permanent teeth to provide an insight into the blood circulation dynamics
B.1.3	Expected duration of project	2 months
B.1.4	Expected start date	December 2019
B.1.4	Expected finish date	March 2020
B.2	**Material and methods (** mandatory to include sample size, statistical methods etc.)**	
B.2.1	Aims of the research project	To evaluate if a modified pulse oximeter can be used to assess pulp vitality

B.2.2	Objectives of the research project	(a) To develop a pulse oximeter capable of measuring oxygen saturation of teeth. (b) Correlate values of oxygen saturation in young permanent teeth, permanent teeth and on finger.
B.2.3	Methodology* * (maximum up to 350 words)	The study is planned to be an observational, cross sectional type to be conducted on patients reporting to the dental clinics. Informed consent is to be obtained. Inclusion criteria: (a) A convenience sample of 80 teeth from children (boys and girls) aged 7-13 (both mixed and permanent dentition) free from any systemic disease, exhibiting Frankel's behavior + or ++ are to be selected for the study. (b) Both anterior and posterior teeth (permanent and young permanent) are to be included wherein tooth must have sufficiently erupted into the oral cavity to enable application of the probe. (c) Teeth selected for the study will be verified by x-ray if the tooth may be classified as a young permanent tooth (root develop from Nolla's stage (6 to 9) or permanent tooth (the root is completed). A pulse oximeter with a finger probe and an ear probe attached to a rubber dam clamp holder, is to be used to gather measurements of oxygen saturation from the finger and teeth respectively after proper isolation. 3 measurements are to be recorded; 1. Finger probe: on the finger (after 30 seconds) 2. Modified ear probe: on the finger (after 30 seconds) 3. Modified ear probe: on the tooth (after 30 seconds) 4. Grouping: A sample size of 30 per group (permanent and young permanent) are to be selected. Control group (n=20) will be readings on teeth wherein root canal treatment has already been performed Statistical analysis: Spearman's correlation test Is to be used to determine the correlation between oxygen saturation levels on finger and teeth using SPSS

B.2.4	**Please-in fill this section if your proposed study is a clinical trial/human based experiment.**

B.2.4 A	Does the study involve use of : Drugs/ Devices/ Vaccines/ drugs from traditional and Alternate Systems of Medicine/ Any other	YES
B.2.4 B	Is it approved and marketed In Saudi Arabia, Europe, USA, or if any other countries, specify	NO
B.2.4 C	Does it involve a change in use, dosage, route of administration?	NO
B.2.4 D	Have any preclinical Studies done? If yes provide data	NO
B.2.4 E	Are you aware if this study/similar No study is being done elsewhere	NO
B.2.4 F	Will you use any biological/genetic/ hazardous materials?	NO
B.2.4 G	Will you use of organs or body fluids?	NO
B.2.4 H	Will you use any form of ionizing radiation/radioisotopes	NO
B.2.4 I	Will any sample collected from the patients be sent abroad? If Yes, justify with details of collaborators	NO
B.2.4 J	Does the anticipated benefits form the study out-weigh the risk?	NO
B.2.4 K	Is there any physical / social / psychological risk or discomfort involved?	YES
B.2.4 L	Is there compensation for participation in the study/in case of adverse effects/toxic effects included?	NO
B.2.4 M	Is there compensation for injury? If Yes, by whom? Provide details.	NO investigator/insurance or any other
B.2.4	References (Maximum up to 5)	Goho C. Pulse oximetry evaluation of vitality in primary and immature permanent teeth. Pediatric dentistry. 1999 Mar;21:125-7.
		Calil E, Caldeira CL, Gavini G, Lemos EM. Determination of pulp vitality in vivo with pulse oximetry. International endodontic journal. 2008 Sep;41(9):741-6.
		Munshi A, Hegde A, Radhakrishnan S. Pulse oximetry: a diagnostic instrument in pulpal vitality testing. Journal of Clinical Pediatric Dentistry. 2003 Jan 1;26(2):141-5.
		Jafarzadeh H, Rosenberg PA. Pulse oximetry: review of a potential aid in endodontic diagnosis. Journal of endodontics. 2009 Mar 1;35(3):329-33.

B.3	**Investigators, collaborations and funding.**	
B.3.1	Expected location (where will the study take place?) of the proposed study (e.g. institution campus, labs, hospital, clinic of ISNC, including community services sites, PHCs, hospitals, polyclinics, research centers, etc.)	ISNC dental clinics

B.3.2	List the expected gatekeepers permissions that maybe required to conduct your study (e.g. ISNCs program head, ISNC hospital /clinic director, MOH, PHCS, hospital treatment and rehabilitation centers community service sites, etc. external to ISNC)	ISNC program head
B.3.3	Collaboration if any (list any other individuals or organizations supporting/ enabling the project e.g. other program, university/ institution, research centers, research labs, etc. external to ISNC)	NONE
B.3.4	Funding sources	NONE
B.4	**Intra-mural Fund (fill in this section ,if you are.seeking fund from ISNC-RC)**	
	purpose	Amount
	staff	
	travel	
	Chemicals/ animals/ kits	
	Equipment	
	Miscellaneous if any	Total
B.5	**Requirement for ethical committee clearance**	
B.5.1	Institutional Ethics Committee (Human/Animal)	Human yes
B.5.2	Are other permissions and approvals required (if the proposed study is outside ISNC (multicenter), this may include other ethics committees, gatekeepers etc.)?	
B.5.3	If your answer to the above question (B.5.2) was yes please specify.	no
B.6	**Facilities and 'Equipment**	
B.6.1	Facilities and equipment currently existing in the institution (provide details)	
B.6.2	Equipment planned to purchase (provide details)	Name of the equipment: purpose Pulse oximeter: The main instrument fot the study
B.6.3	Equipment and facilities available in the proposed site of collaboration (institution/ hospital/research center)	None

Section C: Project Gantt chart

		Project duration in months ,

Research Team Members	Role in the project	4													
1. Principle Investigator	Literature Review	1													
	Data Collection	1.5													
	Data Analysis	0.5													
	Drafting manuscript	1													
2. Co-Investigator1/ Research Assistant!	Literature Review	1													
	Data Collection	1.5													
	Data Analysis	0.5													
	Drafting manuscript	1													
3. Co-Investigator2/ Research Assistant2	Literature Review	1													
	Data Collection	1.5													
	Data Analysis	0.5													
	Drafting manuscript	1													
4. Co-Investigator3/ Research Assistant3	Literature Review	1													
	Data Collection	1.5													
	Data Analysis	0.5													
	Drafting manuscript	1													
5. Co-Investigator4/ Research Assistant4	Literature Review	1													
	Data Collection	1.5													
	Data Analysis	0.5													
	Drafting manuscript	1													
6. Co-Investigator5/ Research Assistant5	Literature Review	1													
	Data Collection	1													
	Data Analysis	0.5													
	Drafting manuscript	1													

Section D: Research Risk Assessment Tool

Note: The Risk Assessment Tool should be used by all researchers (students and staff) at ISNC to determine the level of risk the research project may carry. **If** the answer is 'YES' to any question on the Risk Checklist below, your study is deemed to be of **high risk**, level. If you answer is 'NO' to all questions on the Risk Checklist, your study is deemed to be of **low risk** level.

Please refer to guidance notes in the table below for each question to assist you in answering the questions in the most appropriate manner.

	Research Risk Assessment Items	Yes	No
A	Does the study involve participants who are particularly vulnerable or unable to give informed consent or in a dependent position (e.g. vulnerable children, your own students, over researched groups, people with learning difficulties, people with mental health problems, young offenders, and people in care facilities, including prisons)?		✓
B	Will participants be asked to take part in the study without their consent or knowledge at the time or will deception of any sort be involved (e.g. covert observation of people in non-public places)?		✓
C	Is there a risk that the highly sensitive nature of the research topic might lead to disclosures from the participant concerning their own involvement in illegal activities or other activities that represent a threat to themselves or others (e.g. drug use, or professional misconduct)?		✓
D	Could the study induce psychological stress or anxiety, or produce humiliation or cause harm or negative consequences beyond the risks encountered in normal **life?**		✓
	Does your study involve **ionizing** imaging techniques such as x-ray radiation, CT, CBCT		✓
E	Does the study involve imaging techniques such as MRI scans or ultrasound?		✓
F	Does the study involve sources of non-ionizing radiation (e.g. lasers)?		✓
G	Does the study involve physically intrusive procedures, use of bodily materials (tissues, organs, body fluids, etc.), or DNA/RNA analysis? (see guidelines for more details)		✓
If 'Yes' to question G, continue below:			
G1	Does the study involve the use or collection of **bodily materials** or tissue from a **human being?**		✓
G2	Does the study involve DNA or RNA analysis of any kind?		✓
G3	Are substances or products to be administered (such as non-food substances or drugs)?		✓
G4	Does the study involve only moderately intrusive procedures (taking less than 40m1 blood, collecting bodily waste, cheek swabs)?		✓
G5	Are invasive, intrusive or potentially harmful procedures not already covered by items G1 - G4 to be used in this study?		✓

Section E: Check List of Attachments to Be Submitted with the Application

E.1.	**General**
Type of Research Project	Attachment in general
I. Questionnaire Based Study	1. Sample question (Arabic and English) in word/PDF format only. N/A 2. Application from Principal Investigator to issue request letter from the Dean to data collection site/s. N/A

2. Clinical (Patient based) Study	1. Consent form (Arabic and English). Yes 2. Sample of sample data collection sheet (Case Performa) Yes 3. Application from Principal Investigator to issue request letter from the Dean to data collection site/s Yes
3. Community Service Based study	1. Copy of Community service proposal N/A 2. Sample of proposed data collection sheet (Performa). N/A
E.2	**Attachments mandatory for researchers EXTERNAL to Ibn Sina National College for Medical studies ONLY, a print copy of the same to be submitted with signed form**
1. Proof of employment	**N/A**
2. Copy of ID card/ IQAMA	**N/A**
3. Copies of proof of educational qualification	**N/A**
4. Proof of pricing details of equipment/ chemicals/ any other material (if applicable)	**N/A**
5. Full copies of papers published in last 5 years	**N/A**

Section F: Principal Investigator's Bio-Data

1	Name	AMIT VANKA
2	Total experience (Teaching/Industrial/Research/Clinical)	18
3	Date of birth	22/03/1975
4	Complete postal address (As per your passport/ID card)	Ibn slna national medical college, room number 362: amitvanka@rediffmail.c phone: 597697765
5	Present address for communication (Should include phone number and e-mail ID)	Ibn sine national medical college, room number 362: amitvanka@rediffmail.c phone: 597697765
6	Educational Qualification	Degree: **BDS** — Institution: Govt. Dental college Mumbai Degree: **MDS** — Institution: College of dental surgery, Maropal academy of higher education
7	Publications from last 5 years (Maximum up to 5 numbers)	Maturogenesis by revesculadzation in an infected Immature permanent tooth. V Arnit, A Jaln, UA Nayak, M Bhat Journal of Indian Society of Pododontics and Preventive Dentistry 32 (2), 172 Initial experiences with NAM - assisted primary repair of the BCLP deformity, S Prase& S Ravindran, V Radhaluishnan, PV Hazarey, A Vanka, B Raj. Special Care In Dentistry 37 (6), 304-308

Section G: Declaration by Investigator/Co-investigators

1. I/We agree and state the information submitted in this application is true to the best of our knowledge.
2. I/We agree to the rules and regulations of ISNC/ISNC's research center/ ethics committees/department.
3. I/We agree to abide by ISNC-RC's research guidelines.
4. I/We agree to sign undergraduate research agreement (if student is involved in the project) before the commencement of the project and agree to honor the signed agreement.
5. Uwe submit expenditure report once in a year and final expenditure report after completion of project/at the end of the duration/end of cancellation of project.
6. I/We submit bills and copies of invoice for every purchase made with the research grant.
7. Uwe submit final research report with raw data to the research center.
8. Uwe submit research publications to the research center.

S. No	**Applicant**	Name	Signature and date
I	Principal investigator	AMIT VANKA	
2	Co-Investigator/research assistant	MOHAMMED JOHN	
3	Co-Investigator/research assistant	HANI AL ZAHRANI	
4	Co-Investigator/research assistant	HAMZA AL WAGDANI	
5	Co-Investigator/research assistant	AHMED AL SHARIEF	
6	Co-Investigator/research assistant	NARIMAN JOHARJI	

Section H: Instructions to form user

General	Use font type: Times New Roman, Font Size: 12, Spacing: 1.15
A.1	I. Mandatory to be a full time staff member of ISNC, this does not include teaching assistants and other tenured employees' e.g. visiting staff. 2. Anyone external to ISNC could be a co-investigator in a research project but never a Principal Investigator.
A.2	1. It is ISNC's policy to include at least 1 student/intern in all the possible research projects. In case student/intern not included, a written explanation should be submitted in a separate word file and submitted as an attachment 2. The number of student/interns included in the research project should not exceed more than 5 student/interns per project
B.1.1	Title should not contain name of the college (ISNC), if necessary, instead could mention as "private higher education institution in Jeddah/K.SA"
B 1.2	Background and rationale of the proposed research project in lay/non-technical language that includes; 1. Summarized literature review 2. A clear statement of the justification for the study, and its significance in development and in meeting the needs of the country/population in which the research is carried out. 3. Summary of all previous studies on the topic, including unpublished studies known to the investigators and sponsors, and information on previously published research on the topic, including the nature, extent and relevance of animal studies and other preclinical and clinical studies. **4. A** brief description of the site(s) where the research is to be conducted, including information about the adequacy of facilities for the safe and appropriate conduct of the research, and relevant demographic and epidemiological information about the country or region concerned

<table>
<tr><td></td><td>5. The potential benefits of the research to subjects and to others
6. The expected benefits of the research to the population, including new knowledge that the study might generate</td></tr>
<tr><td>B.1&2</td><td>The objectives of the trial or study, its hypotheses or research questions, its assumptions, and its variables</td></tr>
<tr><td>B2.3</td><td>A structured methodology should ideally include the following:
<table>
<tr><td colspan="2">Methodology</td></tr>
<tr><td>I. Design</td><td></td></tr>
<tr><td>2. Setting</td><td></td></tr>
<tr><td colspan="2">3. Subject</td></tr>
<tr><td>- Sampling technique</td><td></td></tr>
<tr><td>- Sample size</td><td></td></tr>
<tr><td>- Inclusion criteria</td><td></td></tr>
<tr><td>- Exclusion criteria</td><td></td></tr>
<tr><td>4. Tools for data collection</td><td></td></tr>
<tr><td>5. Outcome measurements</td><td></td></tr>
<tr><td colspan="2">6. Statistical analysis</td></tr>
<tr><td>-Software proposed to be used</td><td></td></tr>
<tr><td>- Statistical subroutines (Tests)</td><td></td></tr>
<tr><td>- Level of significance</td><td></td></tr>
</table>
Items to be considered to write the above structured methodology depending upon the type of study proposed are as follows;

I. A detailed description of the study/trial design. In the case of controlled clinical trials the description should include, but not be limited to, whether assignment to treatment groups will be randomized (including the method of randomization), and whether the study will be blinded (single blind, double blind), or open. In case of Questionnaire based study the description of validity of questionnaire, pilot testing, etc.
2. Type of sample and the number of research subjects (sample size) needed to achieve the study objective, and how this was statistically determined
3. The criteria for inclusion or exclusion of potential subjects, and justification for the exclusion of any groups on the basis of age, sex, social or economic factors, or for other reasons
4. The justification for involving as research subjects any persons with limited capacity to consent or members of vulnerable social groups, and a description of special measures to minimize risks and discomfort to such subjects
5. The process of recruitment, e.g., advertisements, and the steps to be taken to protect privacy and confidentiality during recruitment
6. Description and explanation of all interventions (the method of treatment administration, including route of administration, dose, dose interval and treatment period for investigational and comparator products used)
7. The investigators' plans and justification with regards to ethical issues arising from the proposed study and how it is proposed to deal with them, such as;
(i) The justification for involving as research subjects any persons with limited capacity to consent or members of vulnerable social groups, and a description of special measures to minimize risks and discomfort to such subjects
(ii) Plans and justification for withdrawing or withholding standard therapies in the course of the research, including any resulting risks to subjects
(iii) Any other treatment that may be given or permitted, or contraindicated, during the study
(iv) Clinical and laboratory tests and other tests that are to be carried out
(v) Rules or criteria according to which subjects may be removed from the study or clinical trial, or (in a multi-center study) a center may be discontinued, or the study may be terminated .</td></tr>
</table>

	(vi) Methods of recording and reporting adverse events or reactions, and provisions for dealing with complications . (vii) The known or foreseen risks of adverse reactions, including the risks attached to each proposed intervention and to any drug, vaccine or procedure to be tested. (viii) For research on pregnant women, a plan, if appropriate, for monitoring the outcome of the pregnancy with regard to both the health of the woman and the short-term and long-term health of the child . (ix) Plans for monitoring the continuing safety of drugs or other interventions administered for purposes of the study or trial and, if appropriate, the appointment for this purpose of an independent data-monitoring (data and safety monitoring) committee. 8. The means proposed to obtain individual informed consent and the procedure planned to communicate information to prospective subjects, including the name and position of the person responsible for obtaining consent. 9. When a prospective subject is not capable of informed consent, satisfactory assurance that permission will be obtained from a duly authorized person, or, in the case of a child who is sufficiently mature to understand the implications of informed consent but has not reached the legal age of consent, that knowing agreement, or assent, will be obtained, as well as the permission of a parent, or a legal guardian or other duly authorized representative 10. The provisions for protecting the confidentiality of personal data, and respecting the privacy of subjects, including the precautions that are in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives without the consent of the subject 1I . Any foreseen further uses of personal data or biological materials I2. A description of the plans for statistical analysis (Statistical Test) of the study, including plans for interim analyses, if any, and criteria for prematurely terminating the study as a whole if necessary .
B.3.1.	Name of the data collection site e.g. ISNC's different programs, Al Jedaani group of hospitals, MOH hospitals, PHCs, during Hajj pilgrimage, community service site, etcs.
B.5.2.	**Other Ethics Committee Include:** ethics committees' of other university, institution, research center, ministry of health, etc. **Gatekeepers Include:** research data collection site gatekeepers such as director of PHC/hospital/clinic, dean/vice deans' of institution, biomedical lab, department heads, etc.

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Date: 1/20/2021
Reference No: 001DP20012021

This Certificate of Participation in Research is issued to

Name: ***Mr. Hani Mohamed Ahmed Al Zahrani***

Academic number: ***1413795***

Research Project Title: ***"Pulse Oximeter: A Diagnostic tool to assess Pulp Vitality."***

Mr. Hani Mohamed Ahmed Al Zahrani **has participated in the following under the supervision of Dr. Amit Vanka**

1.	Writing Research Proposal	Yes
2.	Conducting Review of Literature	Yes
3.	Collecting the Research Data	Yes
4.	Entering the Research Data	Yes
5.	Analyzing the Research Data	Yes
6.	Drafting Publication Manuscript	Yes

The above mentioned research project was approved by the research center of Ibn Sina National College.
Protocol Identification Number: *022DP17122019*
Approval/Registration. Number: H - *08 – 22122019*

Verified and prepared by (Dr. Siddiq Ahmed):

Dr. Amit Vanka

Associate Professor; Department of Preventive Dental Sciences
Ibn Sina National College for Medical Studies,
Jeddah, Saudi Arabia.

Dr. Irfan Adil Majid

Director of ISNC Research Center
Ibn Sina National College for Medical Studies,
Jeddah, Saudi Arabia.

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The following members of the Ethics committee were present in the meeting held on 22nd December 2019.

Sr. No.	Name	Role in Ethics committee	Qualification	Gender	Attendance (Yes /No)	Affiliation to Institute.
1	Prof. Nasr Arafat Belacy	Chairman	MD, Physiology	Male	Yes	Chairman, Department of Physiology and Islamic Scholar.
2	Prof. Fathi El-Gamal	Member	PhD(England), MD(Egypt), Occupational Medicine	Male	Yes	Chairman of Community **and** Family Medicine
3	Prof. Mohammed Elmoselhy	Member	PhD, Pharmacology, MSC Pharmacology	Male	no	Professor, Department of Clinical pharmacy and Pharmacology
4	Dr. Yasser Bala·	Member	MD, Internal Medicine	Male	no	Associate Professor of Internal Medicine
5	Dr. Hani Atwa	Member	MD, Medical Education	Male	Yes	Head Medical Education Unit
6	Dr. Irfan Adil Majid	Member	MDS Oral Medicine and Radiology	Male	Yes	Chairman, Research Committee
7	Dr. Abidullah Khan	Member	Pharmacology	Male	Yes	Assistant Professor

We approve the research project to be conducted as detailed in the submitted protocol. The Investigator/co-investigator participating in this study did not take part in the decision making or voting procedure for the approval of this study.

If the research project involves clinical trial, it should be registered with ***Saudi Clinical Trials Registry*** before commencing it. The Institutional Ethics Committee and other relevant authorities should to be informed about the progress, any serious adverse event (SAE) occurring in the course of the study and a copy of the final report. Any amendment of the approved protocol, patient information/informed consent and the research team should not be undertaken without prior approval of the committee.

This Institutional Ethics Committee functions in accordance with the "Implementing Regulations of the Law of Ethics of Research on Living Creatures" in Kingdom of Saudi Arabia and other applicable national and international regulations.

This approval is valid for one year only, commencing from the date of the letter.

Prepared by (Dr. Divya K.T.):

Yours Sincerely,
Prof. Nasr Arafat Macy
Chairman, Institutional Human Ethics Committee ,
Ibn Sina National College for Medical Studies,
Jeddah, Kingdom of Saudi Arabia

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Date: 23/12/2019 **IEC Ref No. : H-08-2212019**

To,
Dr. Amit Vanka,
Department of Preventive Dental Sciences,
Ibn Sina National College for Medical Studies,
Jeddah, KSA.

From,
Institutional Ethics Committee,
Ibn Sina National College for Medical Studies,
Jeddah, KSA.

Subject: Approval of research project.

Title of the Protocol: "Pulse oximeter: a diagnostic tool to assess pulp vitality. "

Protocol Identification: 022DP17122019

Sponsor: Ibn Sina National College-Research Center (ISNC-RC)

Dear Dr. Amit,
The Institutional Research Ethics committee has reviewed and discussed your application to conduct the above mentioned research work at the site mentioned in your protocol submitted to the research center, with yourself as the Principal investigator.

The Following documents have been reviewed and approved: List of the all the documents which are submitted to Institutional Research Ethics Committee.

Sr. No.	Name of the Documents	Version No. & Date
1.	Application for Approval/Registration of Research Proposal	-1- 17/12/2019 .
2.	Applications of institutional ethics committee approval	-1-, 17/12/2019
3.	Evaluator's report	-1-
4.	Patient Consent	-1-

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