KING SAUD BIN ABDULAZIZ UNIVERSITY FOR HEALTH SCIENCES
COLLEGE OF DENTISTRY (COD)

INTERNAL POLICY & PROCEDURE

Subject: Conducting Research at the College of Dentistry (COD)		
Dates: Original: 15 December 2019	**Last Revised:** 22 December 2022	**Effective:** 02 January 2023
Reference: KSAU-HS/KAIMRC/MNG-HA	**Replaces Number:** KSAUHS-COD-2021-00009682	
Target Employees / Departments: Faculty, Staff, Interns and Undergraduate and Postgraduate students who are involved in research at COD		***Page 1 of 9***

1. PURPOSE

This policy describes responsibility, guidelines and procedures of research conducted by faculty, staff, interns and undergraduate and postgraduate students at COD, King Saud bin Abdulaziz University for Health Sciences (KSAU-HS) to create conditions for good research practice.

2. DEFINITIONS

2.1 Authorship: Refers to the state or act of writing, creating or substantially contributing to a manuscript and/or the scientific research of a manuscript and in the context of this IPP, to include research proposals.

2.1.1 Author: Refers to the originator of any written work or an individual who has substantially contributed to any written work and also shares responsibility and accountability to said work.

2.1.2 Co-author: Refers to author but the name is usually not the first in the author list.

2.1.3 Corresponding author: Refers to individual that assumes the role of the senior author or the first author, who communicates with journal editors and readers, provides specific information on the contribution of all co-authors, ensures that all co-authors are aware of and approve the submission of the manuscript for publication.

2.1.4 First or primary author: Refers to the individual who has carried out the majority of the work being reported.

2.1.5 Senior author: Refers to an individual who directs, supervises and guarantees the authenticity of the work reported and implicitly takes responsibility for the scientific accuracy, valid methodology analysis and conclusions.

2.1.6 Authorship conflict: Refers to when an author(s) perceives their intellectual contribution or role to a scientific/research work is not given due recognition.

2.1.7 Gifted authorship: Refers to including co-authors that did not provide any contribution to the research work.

2.2 Clinical Research: Refers to a branch of medical research that determines the safety and effectiveness of medications, medical devices, diagnostic products and/or treatment regiments intended for human use.

2.3 Clinical Trials: Refers to a set of tests in medical research and drug development that generate safety and efficacy data for health interventions, e.g., drugs, diagnostics, devices and protocols.

2.4 Critical revision of manuscript: Means reviewing the manuscript by making sure it is deemed appropriate and meets journal submission requirements.

2.5 Essential Documents: Refers to documents that allow on individual and collective bases to evaluate the conduct of a study and the quality of the data produced.

2.6 Faculty Member: Includes Professors, Associate Professors, Assistant Professors, and Lecturers who are working in the university in full-time position.

2.7 Informed Consent: For the purpose of this IPP, refers to the process by which a subject voluntarily confirms their willingness to participate in a particular study, after having been informed of all aspects

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of the study that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated "informed consent" form (ICF).

2.8 Institutional Review Board (IRB): Refers to an independent body composed of medical, scientific and non-scientific members whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved a research studies. It has the right to terminate or suspend research study based on ethical grounds, violation of patient rights or safety.

2.9 International Conference of Harmonization/Good Clinical Practice (ICH/GCP): Refers to an international ethical and scientific standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected.

2.10 Joint-Academic Appointee: Includes any staff with an affiliation from the hospital and/or KAIMRC who is credentialed to work in the COD with a part-time position.

2.11 Research Funding Committee (RFC): Refers to a committee responsible for review and approval of fund requests for conducting research projects.

2.12 Research Misconduct: Refers to fabrication, falsification, plagiarism, or deception in proposing, carrying out or reporting results of research.

2.12.1 Publication misconduct: Refers to plagiarism, fraud, fabrication, falsification, duplication and gifted authorship in reporting a research.

2.12.2 Duplication: Refers to publication of a paper that overlaps substantially with one or more already published without clear reference to the previous publication.

2.12.3 Fabrication: Refers to an intentional act of making up data and misrepresenting research results.

2.12.4 Falsification: Refers to manipulating research materials or changing research data without scientific justification.

2.12.5 Fraud: Refers to deliberate deception, usually the invention of data.

2.12.6 Plagiarism: Refers to the copying of ideas, data or text (or various combinations of the three) without permission or acknowledgement.

2.13 Research Office: Refers to a section of King Abdullah International Medical Research Center (KAIMRC) which is responsible for processing, scientifically reviewing, and approval of all research studies conducted by or within MNGHA.

2.14 Research Study Protocol: Refers to a document that describes the objective(s), design, methodology, statistical considerations and organization of a trial. The research study protocol usually gives the background and rationale for the trial; however, these may be provided in other protocol referenced documents.

2.15 Research Team: Refers to all members of the research study identified and stated in the approved research protocol.

2.15.1 Principal Investigator (PI): Refers to an individual or group of individuals responsible for the conduct of a research. He also prepares, develops and submits research proposal(s) for review by the Research Office.

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2.15.2 Sub-Investigator: Refers to any individual member of the research team designated and supervised by the PI at a study site to perform critical research project-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).
2.15.3 Research Assistant: A member of the research team with a bachelor, or master's degree.
2.15.4 Research support team: Refers to any member who is not identified in the study protocol, but supports the research study as a part of their job responsibility (e.g. editing the manuscript, conducting a laboratory test in the research lab, review of research proposal by KAIMRC, etc.).

2.16 Source Documents: Refers to original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

3. RELATED REFERENCES

3.1 APP 1433-37: Conducting research studies.

3.2 APP 1436-01: Research authorship and publication conduct.

3.3 APP 1441-03: Data access and ownership for research purposes at MNG-HA.

3.4 USRB Policy No. 7: Plagiarism prevention policy and procedures.

3.5 COD-IPP: Academic Integrity and Plagiarism Prevention.

4. POLICY STATEMENTS

- **GENERAL**

4.1 The concept of "research ethics" refers to a broad set of standards, values, and institutional arrangements that contribute to constituting and regulating research activities. These include the duty of honesty in research as well as responsibility to colleagues, other people, animals, the environment, and society in the widest sense.

4.2 The fundamental culture of research is the search for fact. At the same time, research ethics underlines that research has a wider social responsibility. Research ethics also concerns relations among researchers and relations between researchers and other people. In addition, research can have consequences for research subjects and the environment. These guidelines attempt to cover all these elements for all those who are involved in research activities.

4.3 The research team members have the following responsibilities:
4.3.1 Conduct high-quality research characterized by scientific integrity, truthfulness, and accountability, and institution must create conditions that promote such practice.
4.3.2 Preserve religious and ethical values in the field of scientific research.

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4.3.3 Take into account the application of the most important elements of quality in the preparation, implementation and dissemination of scientific research.
4.3.4 Gain international respect for the scientific research sector in the college.
4.3.5 Protect the confidentiality and privacy of all screened and enrolled research subjects.

4.4 The Principal Investigator (PI) has the following responsibilities:
4.4.1 Select and identify the research team members.
4.4.2 Ensure proper protection of research subject's rights, safety and well-being.
4.4.3 Guarantee that all involved members play a role in the research study.
4.4.4 Conduct the research study in a systematic and orderly manner, and ensure compliance with all relevant policies, national laws and related international regulations.
4.4.5 Respond to all data queries related to the study generated by the COD research committee.
4.4.6 Not initiate any research study and/or recruit any research subjects without obtaining the approval of the institutional review board (IRB) on the research protocol and other study documents, as applicable.
4.4.7 Initiate study procedures no later than ninety (90) days from IRB approval or ninety (90) days from the release of funds, if applicable.
4.4.8 Ascertain the validity of the IRB approval which is typically valid for one (1) year.
4.4.9 Inform the research office, IRB and research funding committee (RFC) in the event of failure to conduct the research study within the specified duration.
4.4.10 Report any deviation from research protocol or changes to the approved protocol to the IRB and research office within five (5) working days.
4.4.11 Report serious adverse events and suspected unexpected serious adverse reaction to the IRB and adverse events in the "case report" form in a timely manner.
4.4.12 Submit request for IRB extension, if necessary.
4.4.13 Ensure that the research work should not exceed 25% of plagiarism (To know more about the available Anti-Plagiarism software in Blackboard, please check https://cod.ksau-hs.edu.sa/blackboard-trainings/).
4.4.14 If the PI is resigning/separating from the College or withdrawing from the project, the IRB must be notified and the project is withheld until a new PI from the research team is assigned and resume responsibilities. The resigned/withdrawn PI can still continue in the project as Sub-Investigator.

4.5 Research study related documents, files and/or records must be retained at the investigational site for at least three (3) years after completion of the study; after which these documentations must be retained in a secure archival facility for at least five (5) years.

4.6 IRB in published works is not a requirement for academic promotion process.

4.7 All research studies are subject to monitoring and evaluation by "KAIMRC research outcome evaluation" Unit (ROEU) (except clinical trials). Clinical trials are monitored by the KAIMRC Clinical Monitoring Unit.

4.8 Students' projects in the "Research courses" of DMD program should be submitted to KAIMRC through the **College of Dentistry' Research Unit.**

- **DATA OWNERSHIP**

4.9 In case the research is funded by the university, data ownership belongs to the university and it holds the copyright for any material produced from its funding. In case of KAIMRC funding, ownership and copyright belongs to the KAIMRC. If the research is funded by an external funding agency, data ownership and copyright should be agreed upon before the start of the project.

- **AUTHORSHIP**

4.10 To qualify for authorship, an individual must be identified on the "research study protocol" and should meet all the following criteria:

4.10.1 Provide substantial contributions to the conception or design, or acquisition, analysis, or interpretation of data.

4.10.2 Contribute to the drafting of the manuscript or had done critical revision of the manuscript for intellectual content.

4.10.3 Grant final approval of the version to be published.

4.10.4 The corresponding author for all research works, publication or scientific communications involving students or interns must be a faculty member who is affiliated with the COD, KSAU-HS.

4.11 Research support team members are not entitled to authorship, unless they have prior written agreement with the Principal Investigator (PI).

4.12 The authors' order must reflect their relative contribution to the manuscript and/or the work being reported or as per the research agreement.

4.13 The following contributions do not qualify for authorship, but must be acknowledged in the paper:

4.13.1 Provide funding, administrative or technical advice, reagents, samples or patient's data

4.13.2 Provide students or technical personnel who perform studies.

4.13.3 Routine collection of data.

4.13.4 General supervision of the research group.

4.14 All acknowledged individuals who are not qualified for authorship must have prior knowledge and consent to have their names included in the acknowledgement list.

4.15 Gifted authorship is not allowed. Everyone in the authorship list must have contribution to the research work.

4.16 In case of failure or delay of one of the research team members in one of the parts or stages of the research deliberately and without a written excuse for a project or exceeding the prescribed period of time to accomplish the task entrusted to him, this shall be deemed as an acknowledgment by that member to withdraw from the research project. When presented at conferences and when published in scientific journals, that member is not entitled to claim all its allocations in the above research project, if any.

4.17 All research works, publication or scientific communications generated by authors working at all MNGHA facilities, KAIMRC and KSAU-HS must use the format of the following affiliations:

COD Full time-Faculty, Interns and Undergraduate and Postgraduate Students	COD-JAA
*a) Department's name, College of Dentistry, King Saud bin Abdulaziz University for Health Sciences, Riyadh, Saudi Arabia (**Mandatory**)*	*a) Department, Ministry of National Guard Health Affairs, Riyadh, Saudi Arabia **(Mandatory)***
*b) King Abdullah International Medical Research Centre, Riyadh, Saudi Arabia (**Mandatory**)*	*b) King Abdullah International Medical Research Centre, Riyadh, Saudi Arabia (**Mandatory**)*
*c) Ministry of National Guard Health Affairs, Riyadh, Saudi Arabia (**Optional**)*	*c) King Saud bin Abdulaziz University for Health Sciences, Riyadh, Saudi Arabia (**Mandatory**)*

- **RESEARCH AND PUBLICATION MISCONDUCT**

4.18 All research works are expected to be the authors' own work following research conduct and publication standards.

4.19 All authors and co-authors must be held responsible and accountable for all acts of research and publication misconduct.

4.20 The authors and co-authors must avoid research and publication misconduct, including but not limited to:

4.20.1 Intentional and/or reckless fabrication, falsification and plagiarism of research/scientific work or misrepresenting data in publications.

4.20.2 Publishing research data without proper approval from IRB for studies that involve human/animal subjects.

4.20.3 Misuse of research funds including misleading, concealing information related to research funds and/or potential conflicts of interest related to research funds.

4.20.4 Gifted authorship and duplicative publication of a manuscript to more than one journal.

4.20.5 Sending the scientific paper to be published to more than one party at the same time.

4.20.6 Ignoring the institution's affiliations.

4.20.7 The corresponding author is a student or intern rather than a COD, KSAU-HS affiliated faculty member, providing that the project is approved by KAIMRC and conducted in the COD.

4.21 In case of research and/or publication misconduct, a research team member should initially communicate with the COD Research Unit via email: research-cod@ksau-hs.edu.sa.

5. PROCEDURES

- **Data Storage**

5.1 The PI is responsible, along with the concerned data keeper, for ensuring that sound plans are in place to safeguard the identity of all study subjects as well as the confidentiality of the collected data.

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5.2 During the research study, the PI will fulfill all requirements as stipulated in APP 1433 37 regarding record management, accountability, retention and documentation of communication.

5.3 Upon completion of the research study, the PI will ensure that all requirements for the management of records are accomplished and submitted in accordance with the relevant provisions of APP 1433-37.

5.4 After three (3) years from the research study closure date, the raw data can be requested by another PI from the concerned data keeper upon approval by IRB.

5.5 Concerned data keeper will inform requester on the availability of the requested data or the reason(s) for disapproval of the request.

5.6 For the requested research data that are protected for the original PI, concerned data keeper will inform the requester of the protection period.

5.7 The original PI will accordingly return the research data to the concerned data keeper after the end of the protection period, which is (3) years from the research study closure or at the end of the extended protection time.

5.8 Lab notebooks should be stored in a safe place.

5.9 Computer files should be backed up and the backup data stored in a secure place physically removed from the original data.

5.10 Biological samples should be properly stored.

5.11 Data that are subject to privacy restrictions must be stored in a safe place accessible only to authorized personnel (We need to define later the data keeper, the storage of data at COD and the Safe place).

5.12 Confidentiality of the study subject should be always maintained.

- **Authorship Agreement**

5.13 At the time of inception of the research work, the team should discuss and define the authorship list and its order in the research team agreement (**Appendix A**). This defined list may be changed at the time of conclusion of the study and the PI must justify it and fill modified authorship agreement (**Appendix B**).

- **Authorship Conflict**

5.14 Any individual who expresses grievance against the authors list or its order will:

5.14.1 First try to resolve the issue with the PI or main author of the manuscript and other co-authors.

5.14.2 If the individual fails to get a satisfactory resolution, he/she will complete the "authorship conflict resolution request" form (**Appendix C**) and submit it to the COD Research Unit for appropriate action.

5.15 The COD Research misconduct subcommittee will deliberate on the request.

5.16 If the case was not resolved by the Research misconduct subcommittee, the Research authorship and publication conduct committee (RAPCC) at KAIMRC will initiate a strictly confidential preliminary enquiry.

5.17 The decision of COD Research misconduct subcommittee chairperson, (RAPCC) at KAIMRC and CEO will be considered final, once approved by COD Dean.

5.18 The aggrieved party will follow-up with the COD Research Unit regarding the status of the conflict resolution request.

- **Research and Publication Misconduct**

5.19 Where there is allegation of publication and/or research misconduct, a research team member should initially communicate with the COD Research Unit via email: research-cod@ksau-hs.edu.sa. The COD Research Unit will forward the case to the Research misconduct subcommittee to investigate the issue; and then, recommendation(s) for any course of action will be submitted to the Research Committee chairperson, then, a report will be created and forwarded to COD Dean for approval.

5.20 If the case was beyond the authority of the Research misconduct subcommittee, the Research authorship and publication conduct committee (RAPCC) at KAIMRC must deliberate and resolve all authorship-related disputes and research and publication misconducts.

5.21 If investigation proves the respondent knowingly engaged in research and/or publication misconduct:

5.21.1 Penalties will be based on the decision of the subcommittee or RAPCC.

5.21.2 If the case was processed by the RAPCC:

5.21.2.1 The CEO will advise the executive director of KAIMRC and chairman of IRB to take appropriate action as well as will notify the Saudi commission for health specialties about the incident, when applicable.

5.21.2.2 Where a research work that has confirmed research misconduct is published, KAIMRC will notify the journal or journal publishers about the misconduct with supporting documentation.

5.21.2.3 In case of extramural funded research study and research done outside program facilities, the study sponsor and research conducting institutions will be notified, held accountable and questioned for the publication misconduct case.

5.21.2.4 Appeal against the RAPCC decision will be allowed and considered if the respondent can present new evidence that merits review of the case.

6. RESPONSIBILITY

All faculty, staff, interns and undergraduate and postgraduate students in the college of dentistry are responsible for the implementation of and adherence to the provisions of this IPP.

7. APPENDIX

Appendix A: Research agreement.
Appendix B: Modified Authorship Agreement.
Appendix C: Authorship conflict resolution request.

Approved.....

King Saud bin Abdulaziz University
for Health Sciences
College of Dentistry
Research Unit

جامعة الملك سعود بن عبدالعزيز
للعلوم الصحية
كلية طـب الأسنـان
وحدة البحث

MEMORANDUM

(G)
(H)

Appendix A

REF. NO. : **(COD – RCH- - 20 – SAH)**

TO : Research Committee Chairperson, College of Dentistry
King Saud bin Abdulaziz University for Health Sciences (KSAU-HS)

FROM :
Principal Investigator (Rank), College of Dentistry
King Saud bin Abdulaziz University for Health Sciences (KSAU-HS)

SUBJECT : **RESEARCH AGREEMENT for Research Project (Title)**

Research Agreement

Research Project Title:
(……)

The principal investigator who is henceforth considered the first party (……..), ID no. (…….) has agreed with the co-investigator(s) who will be considered the participating parties cooperate in conducting the research project that is entitled above with the following terms and conditions:

Research Conduction:

1- All parties should maintain scientific integrity, accuracy, and sincerity through all research stages.
2- All parties must commit to the tasks entrusted to him/her by the principal investigator to complete the research as required by the research department at all stages (preparation of the research plan -data collection and analysis - writing the manuscript), which is within the capabilities of the involved parties.
3- Involvement of the contributing parties in the research should be significant. This includes participation in preparing the necessary reports needed by the research office.
4- All parties should commit to accomplishing the research within the agreed period.

Research Presentation and Publication:

5- The first party should document to list all parties' names among the authors of the published work relevant to the research project.
6- In case of failure or delay of the participating parties in one of the parts or stages of the research deliberately and without a written excuse or exceeding the allocated period of time to accomplish the task entrusted to him/her, this shall be an evidence against the participating party to be withdrawn from the research project where he/she is not entitled to claim the research project products (such as conference presentation and published works), if applicable.
7- No party has the right to disclose any information pertaining to the above research project to any entity, whether individuals, groups, or establishments, without a written consent from the whole research team members.
8- The authors' sequence shown below will be reflected in conference presentations and publications unless agreed otherwise. In this case, the first party must sign a "Modified Authorship Agreement" form with the modified authors' sequence.

9- The participating parties shall not be entitled to claim any amendment except with the consent of the first party and all members of the research team. The participating parties shall not have the right to demand the publication of the research in any scientific journal or publish the research or parts of it without the consent of the first party and other research members.
10- The signing of this contract, represents the agreement of the parties to university scientific Research Ethics and all of the above.
11**- In projects with students' and / or residents' involvement, the corresponding author should be a faculty member affiliated with COD-KSAU-HS.**

The following investigators agree to participate in the above-mentioned research project:

Name of Investigator (s) Based on Authors' Rank	**Job Title**	**Affiliation (Department/Collage/University)**	**Signature (s) "Mandatory"**
Principal Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			

***By signing this, the principal investigator must submit the approved IRB once received*.**

Thank you and Best Regards,

Approved by:

Research Committee Chairperson

Date:

Cc: Related Research Team

(G) DD Month 2021

Ref# COD-RCH-000-2021

(H) DD Month 1443

Appendix B

MODIFIED AUTHORSHIP AGREEMENT

College of Dentistry – Research

Research Assts. ☎ 4299999 x 95851 Mail Code ✉ 3183 E-mail 💻 Research-cod@ksau-hs.edu.sa

To be completed by the Principal Investigator			
Principal Investigator:		Badge Number:	
Research Project no:		Approved IRB Date:	
Research Project Title:			
Old Sequence	**Modified Sequence**	**Justification**	**Signature**
Principal Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
Co-Investigator (Full Name)			
The purpose of this modified sequence:			
○ Presentation (Write the title)			
○ Publication (Write the title)			
○ Other			

(G) DD Month 2021 **Ref# COD-RCH-000-2021**

(H) DD Month 1443

To be completed by the Research Committee	
COMMENTS:	
Meeting No:	**Date:**
☐ **APPROVED**	☐ **DISAPPROVED**
Name and signature **Committee Chairperson**	**Date**

REQUEST STATUS		
COMPLETED BY:	**SIGNATURE**	**DATE**
COMMENTS:		

Cc: Related Research Team

Attachment: Research Agreement documents copies

Kingdom of Saudi Arabia
Ministry of National Guard - Health Affairs

المملكة العربية السعودية
وزارة الحرس الوطني - الشؤون الصحية

Appendix C

Authorship Conflict Resolution Request

This form assists the author(s) convey their authorship conflict to the Authorship and Publication Conduct Committee.

☐ ***I have read and understood the provisions stipulated in APP 1436-01: Authorship and Publication Conduct.***

Requester Name : ..... Badge No. : .....

Mobile No. : ..... E-mail : ..... Ext. No. : .....

Protocol No. : .....

Publication Title : .....

.....

.....

I am a member of the:

☐ ***Research Team*** ☐ ***Support Team*** ☐ ***Other :*** .....

Explain the Issue in Detail :

Indicate Your Role in The Study/Publication :

☐ *Substantial contribution to the conception or design of the study.*

☐ *Acquisition, analysis, or interpretation of data.*

☐ *Drafting the manuscript.*

☐ *Revising the manuscript critical for intellectual content.*

☐ *Providing funding, administrative or technical advice regarding reagents, samples or patient data.*

☐ *Providing students or technical personnel who perform studies.*

☐ *Routine collection of data.*

☐ *General supervision of the research group.*

- Attach any communication or agreement with the Principal Investigator (PI)/main author regarding your contribution to the project that supports your claim.
- Attach a copy of the publication.

Requester Signature **Date**