Introduction:

This policy aims to set the required regulations and guidelines for staff &researchers participating in research at the Royal hospital. It promotes ethical research practice and ensures that the researchers comply with the highest international ethical standards. It is intended to provide:

1. Research integrity framework
2. A structure to protect both researchers and participants
3. A guide on information sharing and patients' data confidentiality
4. A plan on data and results ownership in co-operative research
5. Regulations about research sponsoring by non-governmental entity.

Scope:

This policy applies to all those who conduct, participate, manage or disseminate the results of research carried out at the Royal hospital.

Roles and Responsibilities:

1. **Scientific Research Committee**

Encourage and motivate health workers to conduct scientific research

Activation of the results of scientific research through health policy development and practical application of research results

Cooperation with governmental and nongovernmental sectors in field scientific research

Organize educational programs to increase the awareness of research.

Ensuring that research in the Royal Hospital is consistent with ethical standards, methods of data collection and impact on patients, as well as optimal allocation of research resource.

Review the ethical conduct of research in the hospital supporting and collaboration with the scientific research committee, and issuing final approvals for research or publication.

The committee will meet monthly and whenever needed.

The committee should submit the recommendations and minutes on a regular basis to DG's office.

2. Research Section

Administrating and maintaining this policy

The section is responsible for provision of training on the current ethical best research practices for all researchers at the Royal hospital.

The section is committed to provide support and guidance to the researchers; to ensure high quality research practice.

3. Principal Investigator/Researchers

A principal Investigator is the person responsible about research integrity and must ensure the following:

- The research is conducted up to the highest national/international ethical standards of a good research.
- Obtain ethical approval before initiation of the research, and that is the prerequisite for any data collection process.
- Ensure that commitment to the research per se does not cause harm to the participants, environment and the health system structure or process.
- Adhere to Oman and international laws.
- Ensure that all research members are trained in research ethics and best research practice standards.
- Submit main research results and recommendations to the Research Section as, at a later stage, it can be shared with the policy makers.
- Send the link of the published paper to the Research Section as soon as possible.

Data

Data production and storage must follow the international standards on research data management; to ensure data integrity.
Patients 'and participants' data confidentiality & anonymity (unless prior consent is obtained) must be preserved at all times.
In order to maintain privacy of the participants, the following procedures can be followed:

- Collect the minimum required information from the participants.
- Data must be processed fairly based on specified purposes, consent from the participants, and hospital requirement to fulfill a task for public interest.
- Codes or pseudonyms to be used instead of names, where fitting, for identification of participants.
- Data must be secured using passwords on electronic files and a safe custody for physical files.

- Data should be saved securely, and can be shared with the research ethics committee or supervisor, when required.
- All paper documents containing personal information must be disposed in a way that protects the identity of the participants.

Data to be stored for a minimum of three years after publication of the results, and for a longer possible time if a scientific interest in the details of the research persist.

Data from studies conducted at the Royal hospital are neither the property of the researcher, who generated or observed them, nor of the principal investigator's. Instead, are owned by the hospital which is held accountable for the integrity of the data even after the researchers would had left the hospital. The hospital has the right to check and validate data to make sure it is generated/collected properly based on national and international standards and the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments ethical standards.

A researcher, who makes a patentable finding, should report to the research committee so the committee takes the proper action and register the finding.

Other researchers of the research group are entitled to access the data which they had helped to obtain and they can use it if they got an ethical approval unless agreement between the team and principle investigator was signed before data collection. The principal investigator should be flexible and cooperative to permit secondary analysis of the data after getting ethical approval.

Co-investigators from other institutions are permitted to access the data which they had helped to obtain after the permission of the principal investigator and the research committee.

4. Ethical Approval

Prior to any research data collection, a formal ethical review by the Research and Ethics Committee of the Royal hospital is required.

When ethical approval from the Central Research and Ethics Committee needs to be granted, a formal letter from the Research and Ethics Committee of the Royal Hospital becomes mandatory, to start any data collection in/from the hospital.

Modification of an approved protocol amid a study or changing the character of an approved study (e.g. changing the study design without prior approval) is improper and could be referred to as research misconduct.

5. Informed Consent

Consent must be obtained from all research participants before data collection. Consent can be obtained through the form attached in Appendix -3. Participants must be aware of the aim and importance of the research. Any associated risk must be explained while taking the consent. A participant cannot be enrolled if he/she without a consent. Special groups' consent (Appendix…..) can be taken from a guardian/caregiver.

The research team should emphasize in the consent that the participant has the right to withdraw from the study at any time after starting the research if they chose to.

1. Authorship &Publication Issues

- The principal investigator of any research has an ethical obligation of making the research findings accessible as soon as possible, following the standards of publication.
- Principles of research ethics must be adhered to while publishing and disseminating research findings.
- Authorship mandates that an author should have participated in at least two of the following. Formulation of the research problem and protocol. Production and Interpretation of the results. Writing of the research paper and should be prepared to defend the publication against criticisms (Appendix 1&2).
- Those who do not fit the criterion of authorship must be acknowledged.
- Researchers shall not add any name of anyone does not fit the authorship criteria in the scientific publication. Additionally, they should not exclude the names of contributors in the research who meet the authorship conditions. It is the role of the principle investigator to ensure the correct authors' names order based on their individual contribution.
- A person's name should not be listed as author without his or her knowledge, permission, and review of the final version of the manuscript that includes the names of all coauthors.
- Researchers must adhere to the local and international ethics and standards of the copyright including the use of citation, referencing, and avoidance of plagiarism.
- An author should not send a manuscript for publication in two or more journals at a time, unless otherwise well justified. Additionally, an author should not divide a research paper that is a self-contained integral whole into a number of smaller papers merely for the sake of expanding the number of items in the author's bibliography

2. ***Conflict of Interest***

All individuals involved in research must declare any potential conflict of interest. It is important to highlight that such conflicts should be reported immediately to the Research and Ethics Committee's Chairperson, to take the appropriate action.

Consideration must be given to any raised conflicts of interest related to the research funding source and the nature of the research project. In case of uncertainty, researchers must consult the Research and Ethics Committee's Chairperson.

Conflicts of interest should be considered when investigators engage with peer review processes.

3. ***Research Misconduct***

Research misconduct includes, but not limited to, fabrication, falsification, Misrepresentation of data, plagiarism, fraud or another misuse of research funds or research equipment and noncompliance with the Research Ethics Policy.

Misconduct in research is unacceptable and researcher known to commit misconduct will be subjected to disciplinary procedure. In addition, and subject to the breach committed, the person who committed misconduct might be legally liable in accordance with enacted Omani laws, bylaws and regulations. Misconduct may lead to penal, civil, disciplinary and/or administrative legal liabilities. In order to avoid legal misconduct, all researchers are encouraged to read, understand, and abide by national as well as institutional regulations related to medical research such as those included in the following:

1. Royal Decree 101/96 (The Basic Statute of the Country)
2. Royal Decree 7/2018 (The Penal Law)
3. Royal Decree 29/2013 (The Civil Transactions Law)
4. Royal Decree 75/2019 (The Law Governing the Practice of the Medical Profession and Allied Health Professions)
5. The National Document of Patient Rights and Responsibilities, Ministry of Health
6. Ministry of Health Codes of Professional Conduct
7. Ministry of Health research regulations and guidelines
8. Ethics of Research Publication, The National Bioethics Committee, 2018
9. Royal Hospital institutional research related policies, procedures, and guidelines

Everyone is encouraged to raise his/her concerns if any misconduct is committed or suspected. Importantly, they must be reassured that they will be supported and appropriate action will be taken. The research committee is responsible to investigate, follow up and take appropriate actions if any misconduct is committed.

4. Co-operative Research

The Research Section must be informed about any co-operating project. Moreover, a progress report on agreed intervals must be submitted to the Research Section.

Ethical approval by the Research and Ethics Committee is mandatory before any data collection.

Any research conducted by external teams must recruit at least one of the Royal Hospital staff as a research member.

The researchers, from the Royal Hospital, are responsible to ensure that the co-operating organization is aware of the research policy of the Royal Hospital. In addition she/he will be responsible about all logistics of the research conduction in the hospital as well as the communication with the research and ethics committee.

Researchers should inform the research participants that data gathered during the course of the research may be disseminated not only in a report but also in different forms for academic or other subsequent publications, and meetings with the co-operating institution within acceptable ethical and legislative regulations.

Any data gathered from the Royal Hospital is owned by the hospital. Further future data analysis and use is possible only after a formal approval by the Research and Ethics Committee if the objectives are not included in the first proposal.

In case the research is aimed or intended to turn to a new product development, and unless otherwise agreed in writing prior to the start of the research, the profits should be divided upon agreements of all parties.

Co-operation must be highlighted in all reports of the research outcomes; and conflict of interest to be cleared from the initial stages.

Note: percentages depend on the amount of work it agreement to be signed in advance.

5. Sponsorship

No sponsorship is allowed without a formal approval from the Director General of the Hospital. The Research Section must be aware of the sponsorship agreement. All financial logistics and fund management issues must be reviewed and approved by the assigned team of the project. The team involves members from both the Financial and Legal Departments.

Prior to any data collection, an ethical approval from the Research and Ethics Committee is mandatory.

Conflict of interest needs to be cleared from the initial stages.

Financial support must be addressed in all reports of the research outcomes, both to acknowledge the support and ensure transparency.

6. Review

The Policy shall be reviewed every year or when required.

Appendix 1: The National Bioethics Committee Guideline
(A copy can be found in Sultan Qaboos University website)

1. Introduction

The recording of research through publication is of great importance to contributors in many aspects such as academic promotion, international scientific reputations and others. This recording is accompanied by great responsibility towards the published work. The author responsibilities and burdens differ according to their contribution to the research. Therefore, before starting the scientific research, all participants in the research should agree on the order of their names in the publications so that no dispute may occur between them. Meanwhile, the principal investigator shall coordinate meetings in this regard, and it is desirable that this agreement between the researchers to be in writing.

These guidelines outline some of the ethical aspects of publishing scientific research.

2. The author

- The International Committee of Scientific Journal Editors has set up the following criterions for authors:
- The author shall be an active participant in the development of research concept, or concept design or analysis, and the interpretation of the data resulting from the research.
- Contribute to write the results of the scientific research, or revise the manuscript scientifically
- Approve publishing the results of the scientific research
- Agree to assume all responsibilities in respect of scientific research, and be able to answer all controversial aspects in relation to that research work.
- The person shall be deemed to be an author (whether employed, a student, or a collaborator from another institution) when the above conditions apply.

The principal investigator may include the names of those who contributed effectively to the research even if they do not meet the above-mentioned criteria. He / she may include the names of young researchers to encourage them to research and assist them

in their research and writing, provided they have a contribution to the research or scientific publication.

PI should not be influenced by the relative status of a person (e.g. Head of the Department/Unit/Director of a hospital/center….etc) to include him/her as an author without a significant contribution to the work.

All researchers contributing to the research or scientific publication and who are considered to be authors are required to sign a consent to participate in the research or publication and complete tasks entrusted to them, and they shall emphasize on the following:

- To read the manuscript before sending it for publication.
- To defend their part of the work when there is any scientific criticism of that part.
- To sign any document pertaining to that scientific publication submitted by the scientific journal, the publisher, or any other body.

3. Corresponding Author

When receiving the first draft of the manuscript, the person responsible for communicating with the scientific journal (Corresponding Author) shall answer the arbitrators' questions and comments, and shall respond to publishing steps whether administrative or technical.

4. Sequence of authors' names in the scientific publication

Scientific publications are subjected to a specific system in the sequence of authors' names that must be agreed upon prior to the commencement of the research. The responsibility rests with the principal investigator in writing an agreement between the researchers specifying the name sequence in the potential scientific publication.

In general, the order in which authors names appear should be determined by the relative size of each individual's contribution. The first name indicates the person who has practically done most of the research activities, and the second name indicates the person who also carried out the research activities but less than the first name. Thus, the names shall be organized according to the amount of contribution in the research until it reaches the last name, which may be the research supervisor. Sequence of authors should not be influenced by the relative status of the contributors (e.g. Head of the department/sections).

4.1. Student-supervisor Research Collaborations

The student (either postgraduate or undergraduate), should usually be the first author when the manuscript is substantially based on the student's research. It's a mandatory for the supervisor to ensure that the student is enabled to make the major contribution such as development of most of the research's ideas, design the studies, and perform extensive analysis of the research findings, in order to be the principle author. However, if the student failed to develop these provisos and depended on the supervisor to do so, then in this case, the supervisor should be merited the principle authorship.
Prior agreement must be made to avoid any conflict between the student and the supervisor/s. All academic institutions must establish guidelines to manage the relationship between the supervisor and the student.

5. The basic principles of research and authorship

- To Maintain accuracy and credibility in all steps of the scientific research or writing, such as presenting the achieved scientific results with absolute credibility without distortion to suit the researcher's objectives.
- To adhere to executive regulations and by-laws relating to research ethics and, if necessary, to obtain approval from Bioethics Committees.
- To compliance with the local and international copyright laws and regulations in force related to writing and publishing royalty, such as indicating citation sources.
- Do not re-publish the same scientific paper in another journal without introducing substantial additions.
- The author or researcher shall not add any name that did not play a role in the scientific publication, or omit the names of contributors in the research who meet the author's conditions mentioned. Moreover, he shall take into account the correct name order.
- Authors should submit manuscripts to only one publisher at a time, if rejected should the manuscript be sent to another publisher

6. Duplicate publication

Duplicate publication refers to publishing the same intellectual material more than once, by the author or publisher. Such publications violate the Copy write and deceive the scientific community. Both the authors and publisher are responsible for such non-ethical behavior.

Authors should not submit identical or substantially similar work if it has already been published in another journal.

If the work has previously been published only as a conference abstract author can republish It on another journal and does not constitute duplicate publication since because publication of full article will introduce substantial changes to the article. But author should avoid 'cutting and pasting substantial amounts of text from their own previously published work.

Re-publication of a paper in another language does not constitute duplication, but should be clearly labeled as a translation.

7. Plagiarism

Plagiarism is defined as taking another person's work and represents them as one's own original work.

Plagiarism applies to both published and unpublished work, as well as print versions of material. It may occur at any point in the research process: from planning to writing for publication.

When another's written sentence/s are copied directly from a source, whether published or unpublished, quotation marks, such as inverted commas, should be used and the source of the quotation referenced. If a paragraph is altered or a paraphrasing sentence/s is/are used the source of the paraphrase must be cited. Any ideas obtained in the form of personal communications from should be acknowledged in the paper.

8. Authoring and collaborations

There are many forms of collaborations in the field of scientific research, and the volume of cooperation varies from one person to another and from a research to another. Therefore, the research team must agree with the collaborators before starting the research project. Not all collaborators have the right to include their names as authors in the scientific publication; this is determined by the extent of cooperation.

For example, a particular collaborator provides the research team with a specific chemical substance. In this case, the name of this collaborator shall not be included in the authors' name list because his/her contribution is very small, especially if the quantity of this substance is little, but the research team should indicate their thanks and gratitude to this collaborator in the scientific publication (acknowledgement)

9. Acknowledgments in the scientific publication

Excluding the authors, acknowledgments should be given to all those who contributed to the success of the scientific publication.

The principal investigator should consult those who were acknowledged in the scientific article and ensure their satisfaction of the words used to thank them. Moreover, thanks and gratitude should go to the institutions that provided financial or material funding required to accomplish this research indicating the number of the research grant(s)whether it was partial or a complete grant.

10. Research Data Archiving

After completing the research, the important data shall be kept in the right way in a safe place so that they may be referred to in the future if necessary. The responsibility shall rest with then principal investigator or the researcher in charge.

11. Resolving Disputes

Any Disputes arising between the researchers must first be resolved within the research team, if possible, and if they did not reach to any agreement, the matter shall be submitted to the direct person in charge who may submit it to higher authorities of the institution.

12. Conflict of interests and disclosure

In order for the researcher, author, or institution not to be involved in personal, financial or other interests affecting the integrity of research or authorship, the following shall be taken:

- Researchers or authors shall disclose conflict of interest in relation to scientific research, especially with those who fund the research, or among members of the research team, or those related to the research or scientific publication.
- The principal investigator, the author, or any person in the research team shall not dispose unlawfully the financial resources and the available facilities to conduct research for his / her own personal interest.

The principal investigator shall disclose any material or moral rewards in respect of the research or publication.

Appendix 2: informed consent template

The attached template forms are the ones developed by the World Health Organization (WHO).
It's not mandatory to use the same; it is only to help the researcher to design a consent form useful in the planned research.
The templates in the following link:
https://www.who.int/ethics/review-committee/informed_consent/en/

Appendix 3: Authorship guideline

Refer to Oman biomedical guideline in Appendix 1

Table 1. A guide for Agreement on Authorship and Names Order

Task	Points
Research idea	3 points
Research designing (objectives, method and protocol, data collection tool, sample size and planned analysis)	1 points for each part
Writing up the research proposal	3 points
Data analysis	3 points
Results interpretation	2 points
Manuscript writing	2 points for each part
Reviewing manuscript	2 points

**Note: The above table may help researcher to reach to an agreement about the authorship and names order. The principal investigator is responsible to count the points and share the total with all research team to declare any disagreement.*

References

Title of book/ journal/ articles/ Website	Author	Year of publication	Page
INTERNATIONAL MARITIME COLLEGE OMAN Policy: Research Ethics Policy available online at:https://imco.edu.om/ar/wp-content/uploads/2019/06/Research-Ethics-Policy.pdf		2019	
World health organization document Code of Conduct for responsible Research in November 2017. Available online at:https://www.who.int/about/ethics/code-of-conduct-responsible-research.pdf		2017	
ETHICS POLICY GOVERNING RESEARCH INVOLVING HUMAN PARTICIPANTS PERSONAL DATA AND HUMAN TISSUE: GENERAL PRINCIPLES AND STATEMENTS document of the university of Sheffield. Available online at:https://www.sheffield.ac.uk/polopoly_fs/1.755691!/file/Ethics_Policy_Senate_Approved.pdf			
University of Pittsburgh GUIDELINES FOR RESPONSIBLE CONDUCT OF RESEARCH. Revised: March 2011 . Available online at:http://www.provost.pitt.edu/documents/GUIDELINES%20FOR%20ETHICAL%20PRACTICES%20IN%20RESEARCH-FINALrevised2-March%202011.pdf		2011	

Review / Revision History

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2			
3			
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Dr. Hasina Al Harthi Royal Hospital	Dr. Nasser Hammad Al Azri Emergency Department, Ibri Hospital	Scientific Research Committee, Royal Hospital