Title: Institutional Review Board IRB Policy			CODE:
Operating Manual:	Interdepartmental Policies and Procedures	**Date Issued:** 27-MAR-2024	**Date Effective:** 27-MAR-2024
Process Owner	**Research Unit**	**Review Date:** 27-MAR-2024	**Revision Number** New

1.0 PURPOSE:

1.1 The primary role of the IRB is protecting the rights, safety, and welfare of the subject/patient

1.2 To assure that data from a study will be accurate and reliable.

1.3 To approve the manuscript before submission to the journal.

2.0 SCOPE:

2.1 All Researches with human, animal, plants subjects or studies that include personal data owned by Almoosa College of Health Sciences, must be obtained at Almoosa College of Health Sciences Institutional Review Board (HMG-IRB). IRB is not just a committee; it is a board and with a legal authority and administration.

Note: Royal Decree No. (M / 59) on 14/09/1431 H, was issued approving the law of research ethics on living creatures, which was prepared by the National Committee of Bioethics. It aims to develop general principles and necessary regulations to deal with living creatures, or parts, or there of genetic material in the field of research, in light of professional ethics and in a manner compatible with the Sharia law.

3.0 DEFINITIONS:

3.1 There are three types of review will be done by Almoosa College of Health Sciences - IRB:

3.1.1 Exempt review: Researches that contain very minimal or no risk (e.g. collecting sensitive information or vulnerable population). Approval can be given by any IRB member with the chairman's approval; exempt reviews do not require a convened committee meeting.

3.1.2 Expedited Review: Research can be approved as "expedited" if it is no more than "minimal risk"; Approval can be given by any IRB member with the chairman's approval; exempt reviews do not require a

convened committee meeting. Expedited review may also be used

when minor changes are proposed to an approved research project during the period for which approval is authorized.

3.1.3 Full Board Review: Research that does not qualify for expedited or exempt review (presents more than minimal risks to subjects) will receive review at a fully convened IRB committee meeting.

4.0 POLICY:

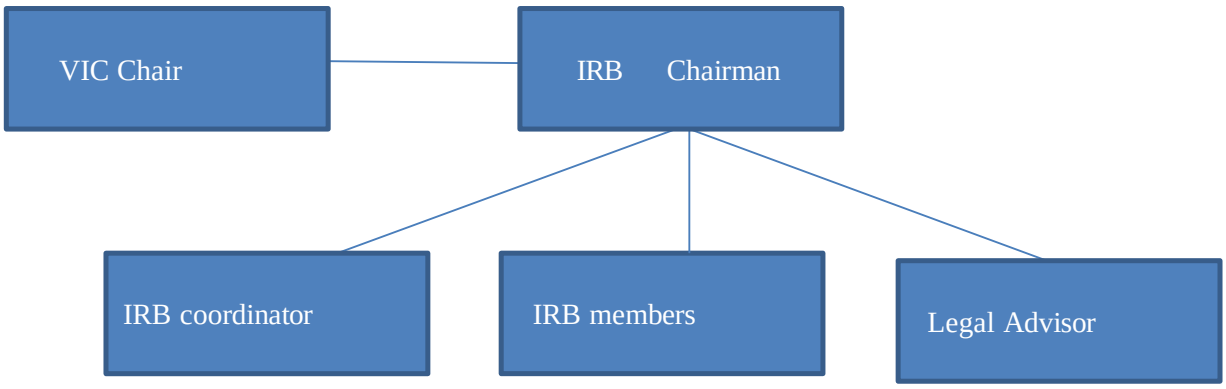
4.1 To comply with the law of research ethics on living creatures, which aims to monitor the implementation of the bioethics research standards, for improvement establish health, preventive, diagnostic, therapeutic and psychological aspects with respect for human dignity, justice, and beneficence, and maintaining individuals' rights, communities as consistent with the Islamic law, traditions and customs of Saudi Arabia as illustrated in the national committee policy.

4.2 Preserving the rights and welfare of subjects at risk in any research activity, whether financially supported or not, and irrespective of the source of any supporting funds, is primarily the responsibility of the institution.

5.0 PROCEDURE:

5.1 **IRB formation:** The IRB is a board formally appointed by the CEO, membership nominations coming from the IRB Chairman. The IRB is formed of a minimum of 10 members to assure complete and adequate review of activities commonly conducted at Almoosa Health Group. The composition of the IRB exceeds the minimum regulatory requirements and is sufficiently qualified through the maturity, experience, and expertise of their members and diversity (experience, expertise, racial, cultural, and gender) of membership to ensure respect for their advice and counsel specific to safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific activities, the IRB is able to ascertain the acceptability of

proposals in terms of organizational commitments, regulations, applicable law, and standards of professional conduct and practice, and community attitudes and are constituted to meet those requirements. All IRB members must be qualified and approved by KACST.



5.2 **Meetings:** IRB shall hold regular meetings every month with at least 70% of its members attending, and should be posted electronically. Researchers are welcome to attend to address specific concerns regarding research protocols but will be asked to leave the meeting during all deliberations and votes. Guests may be asked to sign a confidentially agreement.

5.3 **IRB meeting minutes**: are recorded in writing in sufficient detail to allow an outside observer to reconstruct protocol specific discussions and determinations.

5.4 **Minutes shall include:**

5.4.1 A record of separate deliberations for each protocol reviewed, resulting IRB actions, and any controverted discussions.

5.4.2 The approval period for each initial review, continuing review and amendment.

5.4.3 A record of attendance for each protocol including the names of members who left the meeting due to a conflict of interest and a notation of such.

5.4.4 The voting record for each protocol and the previous meeting's minutes reflecting the number of members for, against or abstaining from the vote and when alternate members replaced a primary member.

5.4.5 The basis for requiring changes to a protocol, tabling or disapproving research.

5.4.6 A written summary of the discussion and resolution of controverted issues.

5.4.7 Justification of deletions or substantive modifications of information concerning risks or alternative procedures contained in Almoosa Health Group approved consent form.

5.4.8 If applicable, summaries of deliberations of protocols for inclusion of vulnerable populations.

5.4.9 If applicable, the rationale for significant risk/non-significant risks device determinations.

5.4.10 If applicable, protocol specific justifications for waivers of consent and research involving vulnerable populations.

5.4.11 A list of all actions that were taken administratively during the previous month.

5.5 **Decisions**: All decisions must be made by the absolute majority (above 51%).

Decisions on research projects should be a) Approved, b) Rejected, and c) Pending Approval

5.6 **IRB responsibilities:**

5.6.1 Conduct reviews of proposal submissions, continuing reviews, and all revisions to protocols of human, animal, and plants subjects.

5.6.2 **Review the scientific, medical and ethical aspects of all research proposals.**

5.6.3 **Weighing relative risks and benefits to subjects through a clear process.**

5.6.4 Approve and reject research activities within Almoosa Health Group, and communicate with PIs within 45 days to inform them with decisions. Decisions on research projects should be a) Approved: by

sending the approval letter, b) Rejected, inform the PI by a regret letter or official e-mail and c) Pending Approval: provide the PIs with amendments need to be done.

5.6.5 Systematically analyze protocols for benefits to subjects and importance of knowledge to be expected and assess the potential benefits in relation to the potential risks involved in the research.

5.6.6 Determine which studies need verification from sources other than the researchers that no material changes have occurred since the previous IRB review.

5.6.7 Observe, or have a third party observe, consent processes and/or the conduct of research.

5.6.8 Ensure prompt reporting of any changes in research activities to the IRB by researchers.

5.6.9 Ensure prompt reporting, by PIs, to the IRB (where applicable) of:

5.6.9.1 Unanticipated problems involving risks to subjects or others.

5.6.9.2 Serious or continuing noncompliance with regulations.

5.6.9.3 Suspension or termination of IRB approval.

5.6.10 Determine if randomized controlled trails need a registration number designated by the Saudi Food and Drug Administration.

5.6.11 Suspend or terminates approval of research not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects.

5.6.12 Be familiar with national and international IRB policies, procedures, regulations, policies, and guidelines relating to research.

5.6.13 Review submitted proposals as assigned by the Chair or Chair's designee.

5.6.14 Review meeting documents in advance of IRB meetings and be prepared for discussion of submitted protocols.

5.6.15 Act as a primary or secondary reviewer of protocols when assigned.

5.6.16 Maintain confidentiality of IRB proceedings.

5.6.17 **Follow up inspection for all researches.**

5.6.18 Disclose conflicts of interest, if applicable.

5.6.19 Attend a minimum of 75% of scheduled meetings.

5.6.20 Activity engages in continuing education related to human subjects' research.

5.7 **FEES AND PAYMENTS**

5.7.1 **IRB allowance:** outside members should be paid an amount of SR 500 per meeting. The total amount would be paid at the end of each year.

6.0 ATTACHMENTS: None

7.0 REFERENCES:

7.1 https://prod.kau.edu.sa/Med/ali/files/Publications/Guide/National_Committe_of_BioEthics_Regulations_of_the_Law_of_Ethics_of_Research_on_Living_Creatures.pdf

8.0 DISTRIBUTION:

8.1 Original in the Research Department.

9.0 REVIEW AND APPROVALS:

Abbas DATE 31-03-2024

NAME: Dr.Abbas Al Mutair

TITLE: Research Center Director

Sign here DATE

NAME: Ms. Omayma Almoosa

TITLE: Administrative Affairs Director

Sign here DATE

NAME: Dr. May Alkhunaizi

TITLE: CEO of Education

Sign here DATE

NAME: Dr. Dalal Altamimi

TITLE: ACHS Dean