Title: Research Informed Consent 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 To ensure the protection of human subjects.

1.2 To control the requirements for participants to be informed of all necessary information and advice with respect to any human subject.

2.0 SCOPE:

2.1 This policy is applied to all clinical prospective studies which involve data collection from human subjects within Almoosa College of Health Sciences premises.

3.0 DEFINITIONS:

3.1 **Informed consent** is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject.

4.0 POLICY:

4.1 All prospective studies that need informed consent must follow King Abdulaziz City for Science and technology, Almoosa Health Group, and Saudi Food and Drug Administration.

4.2 Researches must provide a description in the proposal how informed consent process will be conducted, sittings, duration, and confidentiality.

4.3 Obtaining informed consent should be seen as not only a legal obligation, but also as an ethical obligation.

5.0 PROCEDURE:

5.1 It is expected that researchers will use the bilingual informed consent from Almoosa Research Center.

5.2 **The patient's consultant will accompany the researcher to obtain the informed consent from the patient before enrolment in the research.**

5.3 **Before obtaining the patient/subjects signature the researcher must provide the following information:**

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5.3.1 A clear statement explanation of the purpose of the proposed research.

5.3.2 The expected duration of the subject's participation.

5.3.3 How the hospital will approve the research.

5.3.4 An explanation of all medical procedures and treatments related to the research or conducted only as a result of running the research.

5.3.5 A description of reasonably foreseeable risks or discomforts that the subjects may encounter, and, if appropriate, a statement that some risks are currently unforeseeable.

5.3.6 A description of possible benefits, if any, to the subject and others which may be reasonably expected. It should be stated that if it is an experimental treatment or procedure, no benefits can be guaranteed.

5.3.7 A statement describing the manner and extent, if any, to which confidentiality of records identifying the subject will be maintained, a statement that the IRB and other entities may inspect the records.

5.3.8 Alternatives that might help him/her.

5.3.9 Information regarding who to contact for answers about the research and in the event, there is a research-related injury (this is generally the principal investigator (PI) or another staff member closely associated with the study). A separate contact, typically Almoosa Research Center, must be named for questions concerning the subject's rights to provide input, comments, or complaints.

5.3.10 **The procedure that must be followed.**

5.3.11 A statement that the subjects' participation is voluntary, that refusal to participate will not involve penalty or loss of benefits.

5.3.12 **The patient/subject and or family should be given an opportunity to ask questions and to take time out to consider the request and to get all the necessary information regarding the research if they wish to do so.**

5.3.13 **The signed consent form must be placed in the patient medical record.**

5.4 If the research involves collection of identifiable private information or identifiable biospecimens, one of the following statements must be included as appropriate:

5.4.1 A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such

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removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject.

5.4.2 A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

5.5 When obtaining the informed consent, the researcher shall observe the following:

5.5.1 Clearly explain all potential outcomes to the human subject or his guardian if the subject is incompetent of the research including harmful ones, if any, which result from withdrawal of the informed consent.

5.5.2 The clarification shall be suitable to the educational level, culture and understanding of the human subject or his guardian, answer any question and ensure via suitable methods all the information provided were understood.

5.5.3 The researcher shall not exploit the conditions of the participants or expose them to any type of coercion or inducement.

5.5.4 If the participant is a patient, a person other than his attending physician shall get his informed consent and document obtaining it in the patient's medical file.

5.5.5 Almoosa Research Center shall assign a person to monitor the obtaining of the consent and may assign a qualified person to attend the interview where the informed consent form is demonstrated, so that to verify compliance with the provisions of the Law and Regulations. The said person shall cosign the consent form upon completion.

5.5.6 The principal investigator shall be responsible for obtaining such consent and he may delegate one of his assistants. If they fail to carry out the procedures required for obtaining the consent, the principal investigator may submit a request to the Almoosa research center to delegate other member who's fully aware of the research project.

5.6 The principal investigator shall issue three copies of the Informed consent form, one for the human subject, one for the Almoosa research center or in the patient's file in the case of a clinical research, and the third one for the principal investigator.

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5.7 Validity of Consent form:

5.7.1 **Although an individual consent form is stamped with the period of IRB approval up to 12 months, the consent does not need to be re-signed by the subject on annual basis if it is explicitly stated in the consent form that the duration of the study will be greater than one year.**

5.7.2 **The informed consent must be re-obtained if:**

5.7.2.1 There is a change in the nature of the research

5.7.2.2 The consent form has been altered or amended since the patient/subject signed in.

5.7.2.3 The patient/subject was a minor at the time of entry into the study and has since attained the age of maturity.

5.7.3 **ASH policy for gaining an informed consent must be followed**.

6.0 ATTACHMENTS:

6.1 Research Consent form.

7.0 REFERENCES

7.1 Informed Consent Tips. (1993). Office for protection from research risks. Retrieved February 8, 2018 from https://www.hhs.gov/ohrp/regulations-and policy/guidance/informed-consent-tips/index.html.

7.2 National Committee of BioEthics (NCBE). (2016). Implementing regulations of the law of ethics of research on living creatures. Second Edition. Second Revised version

8.0 DISTRIBUTION:

8.1 To Almoosa Specialist Hospital Staff and Almoosa Health Sciences College's Staff and Students.

8.2 Original in the Research Center.

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9.0 REVIEW AND APPROVALS:

DATE 31-03-2024

NAME: Dr Abbas Al Mutair

TITLE: Research Center Director

Sign here DATE

NAME: Ms. Omayma Almoosa

TITLE: Administrative Affairs Director

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NAME: Dr. May Alkhunaizi

TITLE: CEO of Education

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NAME: Dr. Dalal Altamimi

TITLE: ACHS Dean

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