مستشفى الملك المؤسس عبدالله الجامعي King Abdullah University Hospital	**Policy Title** **Human Subject Research**	
Policies and Procedures Manual **Administrative**	**Originating Department/ Committee: Institutional Review Board (IRB)**	
Policy No.: GM7601	**Page 1 of 4**	
Date Originated: 1/4/2009	**Last Revision: 9/5/2024**	**Issued No.: 9**
Approved by: Chief Executive Officer (CEO)	**Approval Date: 19/5/2024**	

Purpose:

- To regulate, coordinate, and monitor all research on human subjects conducted at King Abdullah University Hospital (KAUH) through IRB process.
- To determine the appropriateness of research on human subjects to the local community and specify the sponsors of the research.
- To protect the rights of patients and their families who participate in the research, and protect their privacy during the research.
- To Maintain the confidentiality of data and information of research participants during and after research conduct.
- Maintain the confidentiality of data and information granted by King Abdullah University Hospital during and after research.

Policy:

- KAUH is committed to providing all available resources needed to support research, such as the place, time, human resources and equipment, with the obligation to protect the rights of healthy volunteers, patients and their families, who participate in research projects, and to protect the confidentiality of research data during and after closing the research.
- The researcher(s) is obligated to maintain the confidentiality of the data and information provided by the founding King Hospital during and after the completion of the research.
- The researcher(s) are obligated to use the data and information for the purposes of research approved by the IRB Committee and King Abdullah University Hospital.
- The researcher(s) are obligated to obtain a new approval from the IRB Committee and King Abdullah University Hospital if they wish to use the data and information granted to him/them in new researches.

Procedure:

A. Scientific research at KAUH is divided into:
   1. Clinical trials: which are conducted on human subjects, intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product.
   2. Non-Clinical Trials: which are conducted on patients and volunteers addressing the efficacy of a medication as well as its pharmacodynamics and pharmacokinetic properties.
   3. Non-Interventional Studies: in which only biological samples are collected.
   4. Surveys: in which data are collected through questionnaires or medical files of participants.

B. IRB Committee:

C. When researches are exempt from the research review process, research proposals are submitted to IRB Committee and evaluated according to the IRB guidelines as published on the hospitals' website.

D. Phases of human subject research approval:
   1. The investigator must comply with the JUST application form for a research protocol.
   2. The investigator applies his/her research to the chairman of IRB to gain the approval through:
      a. The directorate or department, if the investigator is from the hospital staff.
      b. The appropriate deanship and department, if the investigator is from Jordan University of Science and Technology (JUST).
      c. The organization to which the investigator belongs if he/she is outside the hospital (KAUH) or the university (JUST).
      d. Pharmaceutical Research Center- Jordan University of Science and Technology (PRC-JUST). All clinical trials that are funded by private or public companies either inside or outside Jordan, which are conducted at KAUH, should be performed through (PRC-JUST). This

center is officially licensed by the Jordan Food and Drug Administration (JFDA). It is responsible for supervising and monitoring research, and coordinating directly with KAUH, IRB, and the JFDA pharmaceutical study committee according to FRC-JUST instructions approved by JUST Deans Council in 2003.

3. The research application is forwarded to the IRB committee by the IRB coordinator to be considered for approval according to the Helsinki Announcement for Clinical Trials, Guidelines for Good Clinical Practice, and a Pharmaceutical Jordan Studies Law.
4. The committee may request expert opinion from appropriate departments or people if needed.
5. The IRB committee replies through its coordinator to the investigator's application by approval or disapproval and the decision is conveyed through the official channels.

6. In case the research is approved:
   - **a.** The investigator complies with laws and regulations (Helsinki Announcement for Clinical Trials, Guideline for Good Clinical Practice (GCP), and A Pharmaceutical Jordan Studies Law).
   - **b.** The investigator complies with the hospital regulations during the research program.
   - **c.** The investigator selects the proper sample to participate in the research.
   - **d.** The investigator should get an identification card from the IRB coordinator, in case his/her research is survey.
   - **e.** Whenever the research required participation of vulnerable patients, including children, prisoners, pregnant women, persons who are mentally disabled, persons who are economically or educationally disadvantaged, and others who may be at risk for coercion an additional safeguard must be included in the study to protect their safety and rights.

E. Monitoring and review of research on human subjects is the responsibility of the Institutional Review Board (IRB), to ensure compliance of the research with the original research protocol all applicable laws and regulations, and ensure protection of patients and subjects rights, through:

1. The investigator is obligated to inform qualified patients to participate in the research through the primary physician, and through the official website of the hospital.
2. Staff may participate in the surveys and investigations in which the only data collection method is questionnaires.
3. The investigator should provide a list of the participants' names in the human subject research to the IRB committee, and this requirement is documented in the approval letter to the investigator.
4. The investigator is obligated to provide the IRB with a final copy of the research results, and this requirement is documented in the approval letter to the investigator.
5. The investigator should provide a list of patients' names and medical record numbers to ensure that signed informed consents are obtained.

F. Protection the rights of participants and their families:

1. The investigator must obtain written informed consents from participants which should contain the following:
   - **a.** Statement indicating the approval of conducting such research by the relevant bodies and authorities.
   - **b.** Explanation of nature and objectives of the research and its duration.
   - **c.** Expected benefits from the participation in the research.
   - **d.** Potential discomforts and risks from the participation in the research.
   - **e.** Alternative treatments and procedures that might help the patient taking the decision whether or not to participate in the research.

f. How to protect the confidentiality of data.
g. Procedures that patients will follow during research.
h. Compensation or medical treatments available if injury occurs during the research.
i. Participation is voluntary and the patient has the right to refuse or withdraw from the research anytime he/she wants, and that will not compromise care or access to the hospital's services.
j. Who to contact with, or in case the participant has any questions about the research or any complaint, she/he may contact the coordinator of IRB committee at the following number (7200600/45102).

2. The investigator must provide a copy of the informed consent in the patient's medical record, if written informed consents were required.
3. In case there is no informed consent, the investigator must inform the coordinator of the IRB committee to take the necessary actions.
4. The IRB committee decides which research projects don't require written informed consents such as non-interventional studies or surveys (Chief Executive Officer approval is required for using hospital data in the research.
5. At times, a research protocol may be altered based on early findings a new version of informed consent is sent from the sponsor after re-approved by IRB committee then signed by patient and kept in his file.

G. The hospital identifies and manages conflicts of interest with research conducted at the hospital which is one of the IRB Committee responsibilities, through:
1. Specifying the requirements for managing conflicts of interest, both financial and nonfinancial.
2. Identifying the individuals, committees, and others for whom the requirements apply.
3. An ongoing education and monitoring process to ensure compliance with the requirements.

H. In case of any violation to the patient right, the research must be suspended until the investigator should correct, eliminate or fix the situation according to Helsinki Ethical Principle for Medical Research involving human subject, Guideline for Good Clinical Practice, National Laws and Regulations.

I. In case of any serious incident related to research involvement:
1. The incident report policy (GM6005) should be applied.
2. IRB Chairman should be informed within 24 hours.
3. IRB should be informed to have an urgent meeting to discuss the incident in order to make the appropriate decision.
4. JFDA should be informed by the PRC-JUST.

J. Circulating the results of research conducted by hospital staff to the relevant hospital departments, so that all relevant hospital staff can see them.

K. Include the results of clinical research in clinical practice if it is proven to be effective in treatment and within the resources available in the hospital.

Definitions:

- **JFDA:** Jordan Food and Drug Administration
- **PRC-JUST:** Pharmaceutical Research Center- Jordan University of Science and Technology
- **KAUH:** King Abdullah University Hospital

Required Documents:

- Research Informed Consent
- JUST Format for a Research
- نموذج إغلاق بحث
- نموذج موافقة المريض على إجراء بحث علمي
- نموذج تفويض بالموافقة على إجراء تقرير وصف حالة
- Case Report Application
- Case Report Consent Form
- نموذج وثيقة القبول للمشاركة في الأبحـاث الجينية
- Certification of Internal Investigator
- Confidentiality and Non-Disclosure Statement

Approval:

- Institutional Review Board (IRB) Chairman

References:

- قانون مؤقت رقم (٦٧) لسنة ٢٠٠١ قانون اجراء الدراسات الدوائية
- World Health Organization (WHO) Good Clinical Practice (GCP) standards
- International Conference on Harmonisation ICH Topic.
- World Medical Association Declaration of Helsinki
- Institutional Review Board (IRB) Manual.