Official Gazette

We Abdullah II Ibn Al-Hussein, the king of the Hashemite kingdom of Jordan,

In accordance with article (31) of the constitution and in pursuance with the Parliament and Senate Council Decision, approve the following Law and order that it be promulgated, and that it shall be added to the laws of the state:-

Law No. (2)
For the Year 2011.
Law of Clinical Studies

Article (1):

This law shall be named the (law of clinical studies of the year 2011). It shall come into force 30 days after its publication in the official Gazette.

Article (2):

The following words and expressions wherever mentioned in this law, shall have the meanings specified hereunder for it unless the context indicates **otherwise:**

The Ministry : Ministry of Health
The Minister : Minister of Health
Administration : Food and Drug Administration**.**
General Director : General Director of Food and Drug Administration
Institutional Review Board Committee: The committee for review of clinical researches and studies, that is formed in pursuance of the provisions of this law in the body conducting these researches.
Clinical Studies Committee: The committee formed for clinical studies at the Administration in compliance with the provisions of this law.
Clinical Studies: Therapeutic and Non-Therapeutic studies conducted on human beings according to the provisions of this law.
Bioavailability: Rate and extent of absorption and availability of the drug or any of its metabolites in blood or its site of action in the body that reflects the availability of the drug in the mentioned site.
Bioequivalence: No clear statistical difference related to bioavailability when compared with other pharmaceutically equivalent preparations.

Reference Drug: Any preparation licensed for the first time for usage worldwide.

Article (3)

Clinical studies are divided into:

(a)- Therapeutic clinical studies: Any clinical study performed on sick or healthy volunteers.
(b)- Non-Therapeutic clinical studies: Any study performed on healthy volunteers in terms of effectiveness, kinetics, bioavailability and bioequivalence of the drug.

Article (4):

(a)- Clinical studies shall not be conducted unless the conducting body have obtained an authorization from the Minister upon a recommendation from the Clinical Studies Committee in pursuance of the provisions of this law.

(b)- Clinical studies shall be conducted by any entity licensed in accordance with the provision of paragraph (a) of this article:

1. Public and Private Hospitals which possess technical potential to provide the required emergency and intensive care, and laboratory tests.
2. Universities, academic institutions, specialized scientific research institutions, and pharmaceutical manufacturing companies, if they have the required technical potential in compliance with clause (1) of this paragraph.
   In case they do not have such potential, any of them may perform the clinical part of the study at authorized Hospitals and centers.

(c)- Analyses of biological samples related to clinical studies shall be done by approved laboratories which have the requirements necessary for conducting such analyses and assure they are accurate and precise**.**

Article (5):

(a) Clinical studies shall not be performed on a human being before obtaining his written vlountary approval (signed consent form) and after undergoing the medical tests to ensure his safety.
The biological samples or any part thereof shall not be used for purposes other than study purposes.

(b) The body requesting permission to conduct a clinical study shall comply with the following :

1. Prepare a protocol for the study that will be conducted, provided that such protocol must include the scientific justifications for conducting the study in addition to any other details specified in this law.
2. Sign insurance contract with an insurance company having business within the Kingdom of Jordan to cover any damage sustained by this study specially those related to the human beings undergoing such study , provided that cases where such contract can be concluded shall be defined with its terms and requirements according to instructions that are issued by the General Director based on the recommendation of the Clinical Studies Committee .

Article (6):

(a)- Basis and requirements for licensing research bodies and approving the laboratories specified in article (4) of this law shall be defined by virtue of instructions that are issued by the General Director base on the recommendations of the Clinical **Studies Committee**.
(b)- The minister, based on a recommendation of the Clinical Studies Committee, may suspend the license issued by him temporarily or cancel it upon committing any violation to this law provisions without prejudice to any other penalty that had been stipulated therein.

Article (7):

(a)- A committee, named (The Institutional Review Board Committee), shall be formed within each of the bodies stated in article (4) of this law, consisting of at least five members from both sexes with enough experience or specialization provided that one of them should be legal advisor in addition to a representative from local community.

(b) 1- Membership of the Institutional Review Board Committee shall be valid for two years, renewable.
2- The Committee shall elect, in its first meeting, the chairman and his deputy.

Article (8):

(a) The Institutional Review Board Committee shall assume the following responsibilities and powers:

1- Assure the authenticity of scientific justifications for conducting the clinical study.
2- Assure that the research team is qualified and capable of performing such study, and to comply with the good clinical practice during study conduction.
3- Approve the study protocol and authorize its conduction and follow up.
4- Assure that volunteers agreed voluntarily to undergo such study.
5-Coordinate with the Clinical Studies Committee and inform the same if any negative ,unknown, or serious side effects related to the drug , which would appear during or after the clinical study .

(b) The Institutional Review Board Committee shall meet, upon a call from its chairman or his deputy upon his absence, whenever necessary. Such meeting is considered legal with the presence of at least two thirds of its members, providing that the chairman or his deputy is among them, and shall take its decisions with majority of its members.

Article (9):

(a)- The body conducting the clinical study shall comply with the following:

1- Form a research team consisting of scientifically qualified members with enough practical experience to perform the study in accordance with its requirements. The head of this team shall be responsible for executing this study in the most proper manner.
2- To ensure the availability of one or more physicians to supervise the conduction of such study and to be responsible for medical care during that.

(b)- The body conducting the study shall be legally responsible for any damages sustained by the volunteer as a result of his participation in the study.

Article (10):

The approval of the Clinical Studies Committee based on the recommendations of the institutional review board committee is a condition to conduct the clinical studies on drugs.

Article (11):

The body conducting clinical studies shall comply with the study protocol approved by Clinical Studies Committee, in addition to "The Declaration of Helsinki" relevant to conducting clinical studies on human beings.

Article (12):

A committee shall be formed at the administration named (Clinical Studies Committee) and chaired by the General Director and the membership of the following:

a- The Director of Drug Directorate. Vice Chairman.
b- The Head of Cinical Studies Division.
c- A pharmacist from the Drug Directorate based on Drug Director's recommendation.
d- Two physicians, one of them to be nominated by the Minister while the other is an internist who is to be nominated by Medical Association Board.
e- The Director of pharmacy at the Royal Medical Services.
d- Five persons representing universities and private sector who are specialized in the field of Drug Kinetics , Analytical Pharmacy, Biostatistics, Clinical pharmacy, Pharmacology, and are elected by a decision from the Minister based on General Director's recommendation for two years, renewable**.**

Article (13):

The Clinical Study Committee shall assume the following responsibilities and powers:

a- To approve the formation of the Institutional Review Board Committee and monitor its work.
b- Evaluate the reports on studies presented to them for their approval.
c- To verify the authenticity of information presented to them and take the necessary actions.
d- To assure that the bodies authorized to conduct clinical studies in pursuance of the provisions of this law, are complying with the principles of Good Clinical Practice and Good Laboratory Practice according to the directions issued by the Minister for this purpose based on Clinical Studies Committee's recommendation .

Article (14):

a- The Clinical Study Committee shall meet whenever necessary, upon a call from the chairman or his deputy in case of his absence, and such meeting is considered legal with the presence of the majority of the members, provided that the chairman or his Deputy is among them, and shall take its decisions either by unanimous voting or by majority (at least seven of its members).

b- The Clinical Studies Committee may form technical sub-committees to help in carrying out its responsibilities and in presenting the recommendations necessary to this respect.

c- **1-** The General Director shall appoint a secretary for the Clinical Studies Committee from the staff of the Drug Directorate in the Administration who is assisted by a number of its personnel.

2- The secretary of the Clinical Studies Committee shall assume the following responsibilities; preparing the agenda, follow up calling for the committee meetings, entering the meetings minutes and decisions, and to follow up the execution of such decisions and archiving the files and correspondences**.**

d**-** The chairman may invite any experienced and specialized persons who he deems fit to participate at debating any matter presented to the committee without having the right to vote.

e- The General Director issues the necessary instructions regarding the required training of the staff working in the clinical studies field.

Article (15):

The General Director may delegate the responsibility of performing inspection visits to the Director of Drug Directorate or any of the Administration staff on any body licensed for carrying out clinical studies at anytime to assure that they are following the provisions of this law.

Article (16):

a- Fees collected for licensing any entity or for approving any Laboratories provided for in article (4) of this law are defined according to a bylaw that is issued for this purpose and should include cases of exemption from those fees.

b- Charges collected by the Administration against the services provided by the Clinical Studies Committee are defined according to the Minister's directions, based on a recommendation from the General Director.
Those charges shall be used to cover any bonuses payable to members of the Committee and any required expenses.

Article (17):

a- Any person who accepts the conduction of clinical studies, supervise or perform the study without complying with the terms and requirements specified by this law shall be punished either by imprisonment of one to three years or by payment of a fine not less than five thousand Jordanian dinars but not more than twenty thousand dinars or by both penalties.

b- Any of the following persons shall be punished by either imprisonment of six months up to one year or by payment of a fine not less than two thousand Jordanian dinars but not more than five thousand dinars, or by both penalties:

1- The physician appointed to supervise conducting a study in case of his absence during this process without the approval of the administartion, or in case of his non-compliance with medical care responsibility required for the volunteers.

2- Any person who tries to conceal any previously unknown or serious side effects of the drug and does not inform the Clinical Studies Committee.

c- Any person not complying with the protocol of the study without any scientific justification accepted by the Clinical Studies Committee will be punished by payment of a fine not less than two thousand Jordanian dinars but not more than five thousand Jordanian dinars.

d- Any hospital, scientific research institution, academic institution, university, or pharmaceutical manufacturing company, carrying out a clinical studies on human beings without being licensed, or any laboratory performing any analysis on the biological samples without being approved according to this law or without complying with its provisions shall be punished by payment of a fine not less than twenty thousand Jordanian dinars, but not more than fifty thousand Jordanian dinars .

e- Any other violation of any of the provisions of this law related to the conduction of clinical studies, whose penalty isn't being specified in this law, will cause the violator to pay a penalty of not more than three thousand Dinars.

f- Penalties shall not be decreased up to the minimum limit; stipulated for in paragraphs (A), (B), (C), (D), and (H) herein when adopting the abated estimated reasons.

Article (18):

Cabinet may issue necessary regulatory systems to execute the provisions of this law**.**

Article (19):

The prime minister and ministers are delegated to execute the provisions of this law.

18/01/2011

Abdullah II Ibn Al-Hussein

Deputy Prime Minister and State Minister Ayman Al Safadi	Deputy Prime Minister and Minister of Interior Sa'ad Hayel Al Srour	Deputy Prime Minister and Minister of Education Dr. Khaled Al Karaki	Prime Minister and Minister of Defense Samir Rifai
Minister of Foreign Affairs Nasser Joudeh	Minister of Energy and Mineral Resources Suleiman Al Hafeth	Ministry of Justice Hesham Al Tal	Minister of Awqaf and Islamic Affairs Dr. Abdul Salam Al Abbadi
Minister of Social Development and Women's Affairs Hala Lattouf	Minister of Agriculture Dr. Tayseer Al Smadi	Minister of Finance Dr. Mohammad Abu Hammour	Minister of Higher Education and Scientific Research Dr. Walid Al Ma'ani
Minister of Culture Nabih Shuqum	Minister of Political Development Musa Ma'aytah	Minister of Transportation Alaa' Batayneh	Minister of Industry and Trade Amer Al Hadidi
Minister of Water and Irrigation Mohammad Al Najjar	Minister of State for Prime Ministry Affairs Dr. Ibrahim Al Omoush	Minister of Planning and international Cooperation Dr. Ja'afar Hassan	Minister of State for Mega Projects Emad Fakhouri
Minister of Labor Samir Murad	Minister of State for Media Affairs Ali Al Ayed	Minister of Communications and Information Technology Marwan Jum'a	Minister of Public Works and Housing Dr. Mohammad Taleb Obeidat
Minister of Public Sector Development Nisreen Barakat	Minister of State for Cabinet (Council of Ministers) Affairs Fares Qatarneh	Minister of Environment Nasser Al Shraideh	Minister of Municipality Affairs Rabha Al Dabbas
Minister of Tourism and Antiquities Zaid Al Gssous	Minister of Parliamentary Affairs Ahmad Tbeishat		Minister of Health Dr. Mahmoud Al Sheyyab