Conducting Drug Studies Law

CLINICAL TRIAL LAW IN JORDAN

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<th>Conducting Drug Studies Law.</th>
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<td>Based on the Constitutional Article:</td>
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**Law Articles:**

**Article 1:**

This law is called Conducting Drug Studies Law for the year 2001 and will be effective 30 days after the date of publication in the National Gazette.

**Article 2:**

The following words and phrases wherever they are mentioned in this law will have their current description as specified below, unless stated otherwise:

- Minister: Minister of Health.
- Ministry: Ministry of Health.
- Governmental Organization: The General Organization for Jordanian Food and Drug Administration (JFDA)
- General Manager: The General Manager of the JFDA.
- Institutional Review Committee: Research and Drug Study Review Committees that’s assembled according to the regulations of this law (see Article 4B (1,2).
- Drug Study Committee: The assembled committee for drug studies in the JFDA according to the regulations of this law.
- Drug Studies: therapeutic and non-therapeutic drug studies that are conducted on human subjects according to the regulations of this law.
• Bioavailability: the rate of absorption of the active drug or any of its active metabolites in the blood or the affected area in the body.
• Bioequivalence: Not having clear differences regarding the bio-availability between the original drug and generics.
• ID Pharmaceutical Product: The product that’s licensed for global exchange for the first time.

Article 3:

The drug studies are categorized as:
A. Therapeutic Drug Studies: Clinical studies that are conducted on sick volunteers and hence, have the potential for direct medical benefits.
B. Non-Therapeutic Drug Studies: Studies that are conducted on healthy volunteers to assess the safety, bioavailability, and biological effects of the drug.

Article 4:

A. Drug studies cannot be conducted until the party gets a permit from the Minister based on approval from the Drug Study Committee according to the regulations of this law.
B. The drug study will be conducted in any of the following institutions by the research team:

1) Public and private hospitals that have the technical capabilities to provide emergency and intensive care as well as any necessary clinical laboratory and diagnostic tests.

2) Universities, academic institutions, specialized scientific research institutions, and pharmaceutical companies provided that they have the technical capabilities according to clause (1) of this paragraph, and where such technical capabilities are lacking, any of the parties can contract to perform the clinical part of the study in any licensed hospital.
C. Analysis of blood and tissues specimens for the drug study should be conducted in any affiliated laboratory that has the requirements to ensure quality and accuracy.

**Article 5:**

A. The drug study cannot be conducted on humans subjects until written informed consent is obtained. Also, the required medical tests will be performed to ensure the safety of the human subjects.

B. The party that’s conducting the drug study is obligated to:
   1. Prepare a formal protocol plan that includes the scientific design for conducting the study and other details mentioned in this law.
   2. Establish an insurance agreement with any working insurance company in the Kingdom to cover the damages that may result from the study, especially injuries to human subjects.

**Article 6:**

A. The requirements and bases to grant permission and approbation of laboratories in article (4) of this law is according to the permit issued by the Minister based on approval from the Drug Study Committee.

B. According to the approval from the Drug Study Committee the Minister can suspend or cancel the permit issued by him in the case of committing any violation of this law.

**Article 7:**

A. Each institution mentioned in article (4) of this law shall form a committee referred to as an Institutional Review Committee, appointing five members of both genders, comprised of medical specialists (e.g. physicians, pharmacists, nurses), a lawyer, and representatives of the local community.
B. 1. The membership duration in the Institutional Review Committee is two years and is renewable.  
2. On the first meeting, the committee assigns from its members a chairperson and a vice chairperson for the committee.

**Article 8: Roles of the Institutional Review Committee**

A. The Institutional Review Committee addresses the following obligations:
   1. Reviewing the scientific design for conducting the drug study.
   2. Reviewing and approving the entire study plan.
   3. Assuring the expertise of the research team, their ability to conduct the study, and their commitment to adhere to good clinical practices for conducting the drug study.
   4. Assuring the voluntary and informed consent of the human subjects.
   5. Reporting to the Drug Study Committee of the JFDA of any adverse events involving the drug that appear during or after the study.

B. The Institutional Review Committee shall meet upon the direction of the chairperson, or the vice chairperson when the chairperson is absent. For the meeting to be official, participation of two thirds of the members is required, including the chairman or the vice chairman. Decisions are reached by a majority vote.

**Article 9:**

A. The party conducting the drug study is obligated to:
   1. Assemble a research team from scientifically qualified members who have the scientific experience to conduct the study according to the study’s requirements. The team’s principal investigator (PI) is responsible for assuring the proper conduct of the study.
   2. Assure the presence of a physician to supervise the study and be responsible for the medical care during the study.
B. Assume the legal responsibility for any injuries that might occur to the human subjects.

**Article 10:**

A. For conducting a drug study on registered ID pharmaceutical products in the Kingdom for this use, the approval of the Institutional Review Committee is required and the JFDA must be informed of such approval.

B. For conducting a study on an ID pharmaceutical product that is not registered in the Kingdom for that use, the previous approval of the Minister is required based on approval from the Drug Study Committee according to the recommendation from the Institutional Review Committee.

**Article 11:**

Everyone conducting drug studies is obligated to adhere to the study protocol as approved by the Drug Study Committee, and according to the Helsinki Declaration regarding the conduct of drug studies involving human subjects.

**Article 12:**

The JFDA will assemble a committee called The Drug Study Committee with the general manager as the president. The membership is as follows:

A. The drug department manager in the JFDA as vice chairperson

B. The laboratory drug affairs department as the assistant manager.

C. The pharmaceutical manager in the royal medical services.

D. Five individuals from universities and private sectors from medical specialists in pharmacodynamics, analytical pharmacy, biostatics, clinical pharmacy, and pharmacology. They are chosen with a decision from the Minister based on approval from the general manager for two years and may be renewable.
Article 13: Roles of the Drug Study Committee

The Drug Study Committee addresses the following duties:
A. Regulating the development of the Institutional Review Committee and monitoring their work.
B. Evaluating the study drug reports presented to committee for approval.
C. Assessing the integrity of the information presented to the committee.
D. Ensuring the commitment of the certified parties for conducting drug studies according to the regulations of this law, by applying good practice regulations for clinical and laboratory tests issued by the minister.

Article 14:

A. The Drug Study Committee meets when determined by the chairperson, or vice chairperson in the case of her/his absence, on an as needed basis. A quorum is established with the participation of the majority of its members, including the presence of the chairperson or vice chairperson. Decisions are made unanimously or by at least five votes [??????].
B. The Drug Study Committee shall assemble a scientific committee to help them conduct their duties
C. 1. The general manager shall appoint a secretary-general for the drug study committee from the pharmaceutical department employees.
   2. The drug study committee’s secretary-general is responsible for the work agenda, sending invitations for meetings, taking the minutes, document decisions by the committee and follows up with them, plus all other necessary documentation concerning the study.

Article 15:

The general manager can delegate authority to the pharmaceutical department manager or any of his employees in JFDAaudit the parties permitted to
conduct the pharmaceutical studies to ensure compliance with the law regulations.

**Article 16:**

A. Who determines the permission fees of laboratory approbation mentioned in article (4) of this law is according to a system issued for this cause that also contains fee exemption cases.

B. Who determines the fees the JFDA gets in exchange for the services of the drug study committee provides according to regulations issued by the minister, and is dedicated for awards for committee members and other expenses.

**Article 17: FINES AND PUNISHMENT**

A. A year up to three years jail sentence or a fine that is not less than 5000 JDs (7,500 $US) and does not exceed the 20,000 JDs (30,000 $US) or both sentences for anyone who agrees on conducting the drug study or supervises it without committing to the requirements of this law.

B. A jail sentence of at least six months and up to a year or a fine that is not less that 2000 JDs (3000 $US) and does not exceed the 5000 JDs (7,500 $US) or both sentences for:

1. The physician appointed to supervise conducting the study is absent at any time during the conduct of the study or if the physician does not commit to the necessary medical care for the human subjects.

2. Whoever intentional fails to report any adverse events to the drug study committee.

C. A fine that is not less than 2000 JDs (3000 $US) and does not exceed the 5000 JDs (7,500 $US) for anyone who does not follow the protocol approved upon by the drug study committee, without a scientific justification.

D. A fine that is not less than 20,000 JDs (30,000 $US) and does not exceed 50,000 JDs (75,000 $US) for every hospital, scientific research institution, university, or pharmaceutical company that conduct drug studies on
humans without permits, as well as any laboratory that analyze vital specimens without committing to the regulations of this law.

E. Any other violation for this law that is related to conducting drug studies and no specific punishment is mention above in this law, the person will be fined not exceeding 3000 JDs (4,500 $US).

**Article 18:**

The Prime Minister can issue the required system to carry out this law.

**Article 19:**

The Prime Minister and ministers are obligated of conducting the regulations of this law.