नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था बिभाग

Regulation of Clinical Trial Research in Nepal

Presenter:

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Director General

Department of Drug Administration

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Drug Act, 2035 (1978)

Chapter 7

Miscellaneous

31. License to be obtained from Department for clinical trial of new drug:

Any person who intends to carry out a clinical trial of any new drug shall obtain license from the Department, as prescribed, for such trial.

Drug Registration Rules, 2038 (1981)

8. License to be obtained for clinical trial of new drug:

(1) If a person intends to carry out a clinical trial of any new drug pursuant to **Section 31** of the Act, such person shall make an application to the Department in the format as referred to in **Schedule-12**.

(2) If, upon making necessary inquiry into the application after it is made pursuant to Sub-rule (1), the Department deems proper to issue the license to carry out the clinical trial of that new drug, it shall issue the license in the format as referred to in **Schedule-13**, by collecting the fees as prescribed in **Schedule-14**.

Drug Registration Rules, 2038 (1981)

9. Renewal fees: The renewal fees as referred to in **Schedule-14** shall be chargeable for the renewal, pursuant to Sub-section (2) of section 11 of the Act, of any license, certificate and recommendation letter issued pursuant to these Rules.

Schedule-12

(Relating to Sub-rule (1) of Rule 8)

Application for license to conduct clinical trial

The Administrator,
Department of Drugs Administration.

Sir,

Whereas, I/we intend to conduct the clinical trial of the following drug; Now, therefore, I/we have made this application, setting out the following matters and affixing a stamp of one rupee hereto, to obtain the license for the same.

1. Of the new drug of which clinical trial is to be conducted:

Name	System	Group or sub-group	Composition	Type or kind	Active ingredient's		Remarks
					Name	Quantity	

2. Of the disease to be suffered by a patient or person on whom clinical trial is conducted:
   (a) Name:
   (b) Method of diagnosis:
3. Of the consumption of the new drug to be administered in the course of clinical trial:
   (a) Method:
   (b) Mode:
   (c) Dosage (daily):
   (d) Period:
4. Mode of clinical trial:–
5. Place where clinical trial is or intended to be conducted:
   (a) Name and address of hospital:
   (b) Name and address of other doctor:
6. Of the person on whom clinical trial is intended to be conducted:
   (a) Name and surname:
   (b) Address:
   (c) Occupation:
   (d) Qualifications:
7. Mention whether the following details of the new drug are attached or not:
   (a) Toxicological report:
   (b) Quality control method:
   (c) Other necessary matters:

Applicant's:
Signature:
Name and surname:
Address:

Date:

Schedule-13

(Relating to Sub-rule (2) of Rule 8)

Government of Nepal

Ministry of Health

Department of Drugs Administration

License for clinical trial

This license is hereby issued, setting out the following matters, allowing the following person to conduct clinical trial of the following new drug, subject to the Drugs Act, 2035(1978) and the Drugs Registration Rules, 2038(1981).

1. Of the new drug licensed for clinical trial:

Name	System	Group or sub-group	Composition	Type or kind	Active ingredient's		Remarks
					Name	Quantity	

2. Of the disease licensed for clinical trial:
   (a) Name:
   (b) Method of diagnosis:
3. Of the consumption of the new drug to be administered in the course of clinical trial:
   (a) Method:
   (b) Mode:
   (c) Dosage (daily):
   (d) Period:
4. Mode of clinical trial:
5. Place where clinical trial is to be conducted:
6. Of the person allowed to conduct clinical trial:
   (a) Name, surname and address:
   (b) Occupation:
   (c) Qualifications:
7. Validity period of license:

License receiver's:

Signature:

Date:

License issuing officer's: Signature: Name and surname: Designation:

Date:

(The matters to be written on t he reverse side of this license.)

Renewal of the license

Certificate				Department's seal	Remarks
Validity extension period		Renewing officer's signature and date	Renewal fees		
From	To				

सि. नं	विवरण	शुरू दस्तुर	नियम ९ बमोजिम नवीकरण शुल्क
८	नियम ८ को उपनियम (२) अनुसार: क्लिनिकल ट्रायल अनुमतिपत्रको लागि	५०,०००।-	०
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NATIONAL GUIDELINE ON CLINICAL TRIALS WITH THE USE OF PHARMACEUTICAL PRODUCTS

Drugs Regulatory Authorities (DRA)

This is the authorized legal body of the government for the regulation and control of drug (i.e. DDA).

1. PROVISIONS AND PREREQUISITES FOR A CLINICAL TRIAL

1.5 Regulatory Requirements

All parties involved should comply fully with the regulatory requirements as specified.

Pre-trial agreement between sponsor and investigator(s) should designate the parties responsible for meeting each applicable regulatory requirement (e.g. application to or notification of the trial to the relevant authority, amendments to the trial protocol, reporting of all adverse events, and notifications to ethics committee).

As per Drug Act 2035 approval for clinical trial should be obtained from DDA in any of the following cases.

- New drug entities
- New indications
- New dosage forms or Route of drug administrations
- New combination of active ingredients
- Unregistered products.

11. ROLE OF THE DRUG REGULATORY AUTHORITY (DDA)

❖ The role of the government is to provide legal framework for clinical trials with aims :

1. To protect the safety and rights of the subjects participating in a trial, and

2. To ensure that trials are adequately designed to meet scientifically sound objectives.

❖ Drug regulatory authorities have mandates :

- to review protocols
- protect the safety of subjects
- to require protocol revisions and/or termination of trials
- on-site inspections of the quality and reliability of the data obtained with due concern for confidentiality.

- Drug Act 2035 clearly states "the need of obtaining the approval letter from DDA for carrying out the clinical trial of drugs, the ethical review board of the NHRC either will invite one expert from DDA during technical reviewing process or send proposal to the DDA for technical review before providing final approval for the proposed clinical trial."

11.2 On-site Inspections

1. As permitted by national CT regulations, drug regulatory authority may carry out on-site inspections of the clinical trial site.
2. Such inspections may be carried out routinely, randomly and/or for specific reasons.
3. Inspection should determine whether investigator has custody of required records or, if not, who has assumed this responsibility.
4. Data archives should be tested for ease of retrieval.
5. Inspections may include data audit.
6. NHRC and DDA should have easy access to all patient files and raw data used for and generated during the trial.

References

1. Drug Act (including latest Amended)
2. Drug Registration Rules (including latest Amended)
3. National Guidelines on Clinical trials with the use of Pharmaceutical Products


धन्यवाद