A Guide of National Medicines and Poisons Board, Clinical Trials Committee (NMPBCTC)

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Acknowledgements

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The National Medicines and Poisons Board acknowledges with sincere appreciation the valuable contributions of the Scientific Review Committee members in reviewing this Guide.

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Preface

This guide describes the procedures guiding the establishment of National Medicines and Poisons Board Clinical Trials Committee (NMPBCTC) in conformity with the World Health Organization (WHO) Guidelines for establishment of Clinical Trials Committee (CTC). The National Medicines and Poisons Board (NMPB) is the authority mandated, by Medicines and Poisons Act 2009, for forming the CTC and to regulate clinical trials in Sudan. This guide explains the basic functions of the committee and its terms of reference in accordance to Guidelines for conducting Clinical Trials on Human and Animal 2017 and Medicines and Poisons Act 2009.

This guide is intended for researchers, universities, and all research centers conducting clinical trials in Sudan. It outlines the procedures for submitting the clinical trial protocol and related documents by the principal investigator (PI) until a decision is issued by the committee. In addition to describing the process of following up and reviewing received periodic reports as part of ensuring the integrity and accuracy of clinical data generated from the conducted trials on humans or animals.

List of Abbreviations

CTC	Clinical Trials Committee
FMOH	The Federal Ministry of Health
GCP	Good Clinical Practice
ICH	International Conference for Harmonization
NMPB	The National Medicine and Poisons Board
NMPBCTC	National Medicines and Poisons Board Clinical Trials Committee
PI	Principal Investigator
SOPs	Standard Operating Procedures

Glossary

Amendment	A change made to the terms of the NMPBCTC application, the protocol or any other supporting documentation after the study has started. A study is normally considered to start with the commencement of any protocol procedures. Note: Some changes may not need the approval of CTC notification.
Assent	A child (12 to less than 18 years old) agreement to participant in research.
Biological Material	Organs, parts of organs, cells and tissues and components of such material from living and dead persons.
Chair	A member of a NMPBCTC appointed to be a Chair by the appointing authority. Where the Chair is unavailable for any reason, his/her duties may be performed by the vice-Chair or alternate vice-Chair.
Good Clinical Practice	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.
Human Participant	An individual living or deceased on whom an investigator conducts research which obtains data through intervention or interaction with the individual, or identifiable private information.
Animal subject	A living animal or deceased on which an investigator conducts research which obtains data through intervention or observation.
Investigator	A licensed professional who acts as an investigator responsible for the conduct of a clinical trial at a trial site, as defined in the trial protocol.

Investigator's brochure	A document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product which are relevant to the study of the product in human\animal subjects.
Principal Investigator (PI)	The investigator who is responsible for the submitted trial site where the study involves specified procedures requiring site-specific assessment (SSA). There must be one PI for each clinical trial site.
Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.
Protocol Amendment	A written description of a change(s) to or formal clarification of a protocol.
Clinical Trial Site	The location(s) where trial-related activities are actually conducted.
The Committee	Refers to the National Medicines and Poisons Board-Clinical Trial Committee.
Clinical Trial/Study	Any investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

1. Introduction

1.1 Purpose

- This regulatory guide defines the operational framework of the CTC under the NMPB, the authority responsible for overseeing CTs in Sudan. It is complied with the principles of the NMPB Guidelines for the Conduct of Clinical Trials on Humans and Animals 2017 and the Medicines and Poisons Act 2009. The guide describes the committee's role in ensuring compliance with ethical, technical, and scientific standards governing clinical trials involving therapeutic and non-therapeutic products, herbal preparations, and new medical devices tested on humans and animals within Sudan.

  The purpose of this guide is to provide researchers with a clear roadmap to achieve study objectives while safeguarding the health, well-being, and rights of participants by supporting Declaration of Helsinki and Good Clinical Practice (GCP ICH). It also highlights the importance of maintaining dignity in the handling and treatment of biological materials, with consideration of scientific procedures and the concerns of the local community. Furthermore, the guide emphasizes the committee's role in minimizing foreseeable risks to research participants, researchers, and the environment.

1.2 Scope

- The scope of NMPBCTC involves ethical, technical and scientific aspects of human and animal clinical trials in Sudan.

1.3 Responsibilities of NMPBCTC

- The NMPBCTC should safeguard the rights, safety, and well-being of all trial participants. Special attention should be paid to trials that include vulnerable participants.
- The NMPBCTC should develop the guidelines for ethical and technical review of clinical trials protocols in Sudan.
- The NMPBCTC is responsible for follow-up of the approved clinical trial protocols through periodic progress reports submitted by the principal investigators or delegated sub investigators; and site visits.
- The validity of this regulatory guide for the below mentioned types of clinical trials that will be conducted nationally, regionally or internationally in one center or multi centers.

  Note: All clinical trials that involve medicinal, herbal products or new devices, shall be reviewed by the NMPBCTC.
- To monitor and evaluate the parties which are permissible to conduct and process the clinical trials on the human and animal, these parties are:

  (A) Universities, academic institutions, specialized scientific research institutions, medicine- pharmaceuticals companies provided that they should have the capabilities for conducting the trials. Moreover, it is permissible, for any of these parties, to conduct the clinical aspect of the study in the public and private hospitals and in the licensed specialized remedial centers wherein the technical capabilities are available for assuming the emergent and prompt care along with

the clinical laboratory investigations deemed necessary for conducting and processing the trials therein.

(B) For the analysis of the biological samples, which pertain to the medicinal trials, shall be conducted and processed in laboratories accepted by the NMPB.

2 The NMP BCTC

2.1 Membership of the NMPBCTC

- The authority of the NMPB shall appoint the chairperson and eventually the members in consultation with the appointed chairperson. The term of the chairperson and members serving on the NMPBCTC can end by resignation, death, termination (e.g.: misconduct, absenteeism - more than 3 consecutive unexplained absenteeism) or completing three years period, renewable twice.
- Members of the NMPBCTC should be trained in research ethics -at least- if they are not expert in this field.

2.1.1 Composition of the NMPBCTC

- The NMPBCTC should be composed of different resource persons concerned with human and animal clinical trial protocols enterprise in the Sudan.
- The NMPBCTC is a multidisciplinary and a multi-sectorial, including persons with relevant but diverse scientific expertise, balanced age and gender distribution, and they have the qualifications and experience to review clinical trials protocols.
- The NMPBCTC consists of 10-12 members, who collectively have the qualifications and experience to review and evaluate clinical trial protocols from an ethical, technical and scientific points of view.
- The chairperson of the committee and most of the members are from outside the NMPB to maintain the independence of the committee.
- One member whose primary area of interest is non-medical.
- One member represents Federal Ministry of Health (FMOH).
- One member represents NMPB. [Preferred to be a clinical pharmacist]

2.1.2 NMPBCTC Independent Consultants:

- The NMPBCTC may call upon experts as independent consultants who may provide review of selected clinical trials protocols, when needed.
- These experts may be specialists in ethics or specific health issues, or methodologies, or represent specific communities, or patient groups or ethnic minority. NMPBCTC consultants are required to give their specialists views but do not take part in the decision-making process, which will be made by the members of the NMPBCTC. Invited experts are expected to sign a confidentiality agreement.

2.2 Declarations of conflict of interest

- Before the first meeting of the NMPBCTC, the chair and members should declare to the committee by signing a written form which will be kept with the rapporteur.

- Before each meeting NMPBCTC chair and members should declare to the committee any material interests they may have in relation to an application for ethical review or any other matter for consideration at that meeting.
- Such a declaration should be made verbally at the meeting, and should be recorded in minutes, prior to the matter being considered, or in writing to the chair prior to the meeting.
- A material interest is any personal or business interest that may, or may not be perceived to, unduly influence the member's or the committee's judgment about the matter concerned.
    - The committee has the following options:

1. The member should leave the meeting room and take no part in the discussion or the vote on the application.
2. The member may remain in the meeting room in order to provide any relevant information requested by other members but may not vote.
3. The member may remain in the meeting room and take a full part in the review, but not taking part in a decision making.
4. The minutes should record any declaration of interest the Committee considers to be material, and its decision on the procedure to be followed. If the Committee is in any doubt, it is recommended that the member should leave the meeting room.

2.3 Procedure of the NMPBCTC

- The officer in charge should review the received application documents in order to check list, then submit it with the full dossier of the clinical trial to the rapporteur.
- The NMPBCTC should receive the full dossier from the rapporteur including the following documents:
    - The main application form filled that consists of the protocol contents.
    - Amendments should be accompanied with a cover letter.
    - Written informed consent form(s) or consent form updates (If applicable) that the investigator proposes for use in the trial, including participants/subject recruitment procedures (e.g. advertisements), written information to be provided to participants.
    - Application form of declaration of the authority responsible for the clinical trial.
    - Clinical trial site evaluation form.
    - Investigator's Brochure (IB) and available safety information.
    - Information about sponsor, payments and compensation available to participants.
    - The principal investigator's current curriculum vitae and/or other documentation evidencing qualifications.
    - Any other documents that the NMPBCTC may need to fulfil its responsibilities.
- The NMPBCTC procedure steps:

1. Receiving the document of the protocol:
   1.1. The principal investigator shall submit a protocol's documents (the proposal and application forms) to the NMPB, and the officer in charge review it according to the check list form No. (PSR-F-03-01).
   1.2. The principal investigator shall submit the documents of the intended clinical trial to the NMPB that include forms No. (PSR-F-03-03), (PSR-F-03-04) or (PSR-F-03-08), (PSR-F-03-05) or (PSR-F-03-07) and (PSR-F-03-06).
2. Assessment of the completion of the document of the protocol:

2.1. The officer in charge shall review the contents of the protocol's documents; uncompleted document must be returned back to the applicant for correction or completion according to the requirements stated in form No. (PSR-F-03-01), then submit all documents to the rapporteur.
2.2. The officer in charge shall review the documents within a period not exceeding one week from the date of receiving the documents according to the form No. (PSR-F-03-02).
2.3. After making sure of completeness of the protocol's documents, it will be submitted to the rapporteur of the committee as soon as possible (2 weeks).
2.4. Acknowledge letter of receipt of protocol's documents should be sent back.

3. Review of the documents:
3.1. The documents of the clinical trial should be presented to the committee for review according to SOPs. No. (PSR-P03).
3.2. The committee may request more information about the proposed clinical trial or invite the principal investigator to meet the committee when necessary.
3.3. The rapporteur issues a letter to the principal investigator to provide the information needed or meet the committee accordingly.
3.4. When the final decision is made, the secretary of the committee should issue a decision letter signed by the secretariat general to the principal investigator.
3.5. The secretary of the committee should notify the principal investigator to receive the committee decision letter.
3.6. In case of approval of the clinical trial, the principal investigator receives an ethical clearance certificate.
4. Reporting and Follow-up:
4.1. The committee may visit the clinical trial site before the start or during the progress of the clinical trial as deemed appropriate by the committee.
4.2. In multi-center trials or large studies, the Committee may require a Data and Safety Monitoring Board (DSMB) to keep the Committee up to date of the balance between risks and benefits.
4.3. The committee should receive progress clinical trial's reports at least every 6 months and the final report after completion of the clinical trial.

2.4 NMPBCTC Rapporteur and Secretariat

The responsible person of clinical trials in the NMPB is the rapporteur and coordinator of the committee.

2.4.1 Responsibilities of Rapporteur and Secretariat

The secretary to the meeting will normally be the committee secretariat. The responsibilities of the secretariat in relation to NMPBCTC meetings are as follows:
Publishing the schedule of the committee meetings:

- Preparing the agenda.
- Allocating lead reviewers.
- Distributing the agenda and papers.
- Recording apologies for absence prior to the meeting.
- Raising in agreement with the NMPBCTC Chair any concern that a meeting may not be quorate.

- Recording attendance of members, deputy, consultants, and observers for the discussion of each application for ethical review.
- Advising the meeting as necessary on compliance with standard operating procedures and, where relevant, the need for the NMPBCTC.
- Making a written record of the meeting (minutes).
- Recording individual votes where a vote is taken on a decision.
- Preparing the minutes of the meeting circulating it before the subsequent meeting for review and approval at the following meeting.
- Notifying applicants of decisions taken at the meeting and taking other follow-up action as necessary.
- Manage and facilitate all official correspondence of the NMPBCTC.
- Preparation, maintenance and distribution of study files.
- Organization of regular meetings and implementing its decision and recommendations
- Facilitate regular and ad hoc meetings in consultation with the chairperson of the committee.
- Archive while ensuring strict confidentiality all project-related protocols, correspondence, decisions and minutes of the committee for a period of at least five years after the completion of the study.
- Communication with the members and investigators.

2.5 Functions and Operations of the NMPBCTC

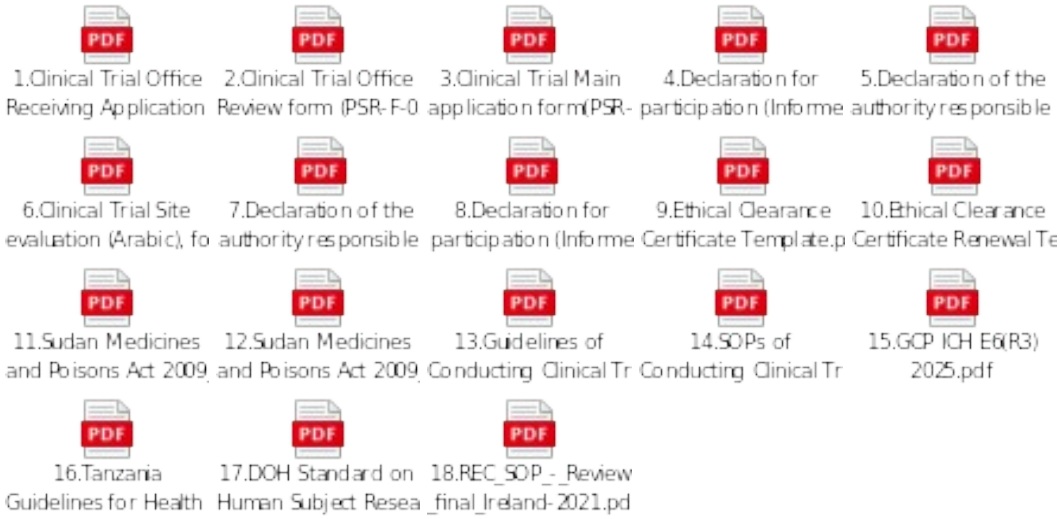
- The NMPBCTC performs its functions according to written standard operating procedures (SOPs). The SOPs should be in compliance with ICH-GCP and with the Medicines and Poisons Act 2009.
- The NMPBCTC makes its decisions at announced meetings at which at least a quorum is present.
- Only members who participate in the NMPBCTC review and discussion should vote/provide their opinion and/or advice.
- Members who have conflicts of interest should declare these to the chairperson (or vice chair as appropriate) prior to the review of the application and these should be recorded in the minutes. In this case, the member may remain in the meeting room in order to provide any relevant information requested by other members, but may not vote.
- The investigator may provide information on any aspect of the trial, but should not participate in the deliberations of the NMPBCTC or in the vote/opinion of the committee.
- The committee meetings may be held on a weekly basis or as appropriate.
- The committee shall be reformed every two years or as required.

3. References

- ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf **Guideline for Good Clinical Practice ICH E6(R3).**
- https://nimr.or.tz/wp-content/uploads/2023/06/GUIDELINES-FOR-HEALTH-RESEARCH-2023.pdf **Guidelines for Health Research 2023 (Tanzania).**
- https://nyuad.nyu.edu/content/dam/nyuad/research/hrpp/standard-operating-procedures/ad-doh-rec-procedures.PDF **DOH Standard on Human Subjects Research - NYU Abu Dhabi.**
- https://www.tusla.ie/uploads/content/REC_SOP_-_Review_final_10092021.pdf **NUI Galway RESEARCH ETHICS COMMITTEE GUIDANCE NOTES on Completing the Application Form.**

4. Attachments

1. Clinical Trial Office Receiving Application, form (PSR-F-03-01)
2. Clinical Trial Office Review, form (PSR-F-03-02)
3. Clinical Trial Main application, form (PSR-F-03-03)
4. Declaration for participation (Informed Consent), form (PSR-F-03-04)
5. Declaration of the authority responsible for the research, form (PSR-F-03-05)
6. Clinical Trial Site evaluation (Arabic), form (PSR-F-03-06)
7. Declaration of the authority responsible for the research (Arabic), form (PSR-F-03-07)
8. Declaration for participation (Informed Consent) (Arabic), form (PSR-F-03-08)
9. Ethical Clearance Certificate Template
10. Ethical Clearance Certificate Renewal Template
11. Sudan Medicines and Poisons Act 2009
12. Sudan Medicines and Poisons Act 2009 (Arabic Copy)
13. Guidelines of Conducting Clinical Trials on Human and Animal (Arabic Copy)
14. SOPs of Conducting Clinical Trials in Sudan 2022, form (PSR-P03)
15. Good Clinical Practice ICH E6(R3) 2025
16. Tanzania Guidelines for Health Research 2023
17. DOH Standard on Human Subject Research, January 2020
18. National University of Ireland (NUI Galway) Research Ethics Committee Standard Operating Procedures 2021



5. Appendix:

5.1 Appendix 1: The Medicines and Poisons Act 2009

Chapter -4
Restriction on conducting & processing the experiments.
Approval for processing the experiments on the humankind
22..

(1) It is not permissible for any person to conduct& process medical experiments, for any medicine or pharmaceutical products and any human except after the approval of the board.

(2) For obtaining the approval, the following must be submitted:

(A) A Scientific document wherein shown the details of the experiments which he intends to process.

(B) A sufficient and an adequate detail about the medicine or product which shall be placed on trial& given to the human, its doses, quantities, method of handling & taking it, type& number of check-ups/ examinations and analysis which shall be processed on the human. This is in addition to the number and age of persons on whom the experiments shall be conducted & processed.

(C) Components/ ingredients of the medicine or pharmaceutical product, its toxics/ poisons, its physiological, biological and clinical effect on the body & its function and all which relates to its effectiveness& effects, its safety on the human body as well as the details of the previous trials & experiments.

(D) Any other statements & information according to which is directed & decided by the board in the regulations.

Giving on permission for conducting & processing the trials/ experiments
23. It is neither permissible to give permission nor to permit conduct & process any medical trials/ experiments on the humankind unless the results of the previously- authenticated scientific and medical trials/ experiments which ere conducted & processed in other countries, that the particular medicine or product caused no harm for the human health in comparison with the used alternatives& substitutes. This is taking, the efficiency & effectiveness of the medicine or product and type of disease, in to consideration.

Approval & consent of the particular person for processing the experiments.
24. It is neither permissible to give permission nor to conduct& process any experiment on any person unless he submits his approval & informing him or his guardian, in case of a minor, clearly, that he is susceptible to undergo medical experiments. This is in addition to making him well- aware of all the

harmful effects which might have resulted from the trials of using the medicine or product along with the number& type/ kind of samples that will be taken from him, check-ups/ examinations and analysis which he shall undergo as well as the guarantees and rights which shall be provided for him.

Processing the experiments on the animal

25. It is not permissible to conduct the trials which pertain to the medicines, drugs and pharmaceutical & veterinary products, clinically, except after obtaining permission from the board pursuant to the regulations.

Responsibility of the party requesting to conduct& process the experiment

26. The person or party, requesting to conduct the experiment, shall be deemed & considered wholly& directly held responsible for any harms &damages which the human or community or environment shall sustain. Accordingly, he shall be obliged to pay all the dues& indemnities/ compensations which result from such harms& damages in addition to any other liability/ legal responsibility.

5.2 Appendix 2: The Guidelines of Conducting Clinical Trials on Human and Animal (Arabic Copy)

بسم الله الرحمن الرحيم

Republic of Sudan
Federal Ministry of Health
National Medicines & Poisons Board
Secretariat General

جمهورية السودان
وزارة الصحة الاتحادية
المجلس القومي للأدوية والسموم
الأمانة العامة

NO. 021378/م ق أ س

لائحة إجراء التجارب الطبية على الإنسان والحيوان لسنة ٢٠١٧م

عملاً بالسلطات المخولة له بموجب أحكام المادة (٤٠) من قانون الأدوية والسموم لسنة ٢٠٠٩م أصدر المجلس القومي للأدوية والسموم اللائحة الآتي نصها :-

الفصل الأول

أحكام تمهيدية

إسم اللائحة وبدء العمل بها

١. تسمى هذه اللائحة " لائحة إجراء التجارب الطبية على الإنسان والحيوان لسنة ٢٠١٧م " ويعمل بها من تاريخ التوقيع عليها .

إلغاء واستثناء

٢. تلغى لائحة إجراء التجارب الطبية على الإنسان والحيوان لسنة ٢٠١٠م على أن تظل جميع الإجراءات التي أُتخذت بموجبها سارية الى أن تُلغى أو تعدل بموجب هذه اللائحة .

تفسير

٣. (١) تكون للكلمات والعبارات الواردة في هذه اللائحة ذات المعاني الممنوحة لها في قانون الأدوية والسموم لسنة ٢٠٠٩ م .

(٢) ما لم يقتض السياق معنى آخر تكون للكلمات والعبارات الآتية المعاني المبينة أمام كل منها :-

"القانون" يقصد به قانون الأدوية والسُموم لسنة ٢٠٠٩.

"المجلس" يقصد به المجلس القومي للأدوية والسُموم،

جمهورية السودان وزارة الصحة الاتحادية الأمانة العامة المجلس القومي للأدوية والسموم

تلفون: ٨٨٠٢٩٥ – ٨٨٠٢٧١ (٢٤٩+) – فاكس: ٥٢٢٢٦٣ – ١٨٣ (٢٤٩+) – ص.ب: ٢١٨ الخرطوم – السودان
Tel.: +249155 880295 - 880271- Fax: +249 183 522263 - P. O. Box: 218 Khartoum - Sudan
E-mail: info@nmpb.gov.sd - website: www.nmpb.gov.sd

"اللجنة"	يقصد بها لجنة إجراء التجارب الطبية على الإنسان والحيوان المنشأة بموجب أحكام المادة ١٣ (١) من قانون الأدوية والسُّموم لسنة ٢٠٠٩.
"حيوانات التجارب"	يقصد بها الحيوانات التي تُجرى عليها التجارب في المختبرات الطبية والمعروفة باسم (Experimental Animals).
" الحيوانات"	يقصد بها الابقار والاغنام و الماعز والابل والفصيله الخيلية والدواجن والحيوانات البرية.
"التجارب قبل السريرية "	يقصد بها التجارب الطبية التي تُجرى على حيوانات التجارب.
" التجارب السريرية "	يقصد بها التجارب الطبية السريرية التي تُجرى على الإنسان والحيوان.
" التوافر الحيوي "	يقصد به سرعة ومدي امتصاص وتوافر الدواء أو أى من مستقلباته الفاعلة في الدم أو موقع تأثيره في الجسم الذي يعكس توافر هذه المواد في موقع التأثير.
" المستحضر الصيدلاني المرجعي "	يقصد به المستحضر المبتكر المرخص لأول مرة للتداول عالمياً.
" دراسة التكافؤ الحيوي "	يقصد بها البحث العلمي والذي يتم فيه مقارنة الدواء المبتكر بالدواء الجنيس المماثل للتأكد بأن المستحضرين لا يختلفا في السلامة والفعالية والتوافر الحيوي عندما يتم اعطائها بنفس الجرعة بنفس طريقة الاستخدام ونفس الشكل الصيدلاني حسب بروتوكول علمي معتمد معترف به من السلطات الصحية العالمية أو حسب ما ذُكر في دليل اجراءات التكافؤ الحيوي السوداني الصادر من المجلس.

أقسام التجارب الطبية

٤. تنقسم التجارب الطبية الدوائية الى ثلاثة أنواع وهي :-

(أ) التجارب الطبية الدوائية العلاجية وهي الدراسات السريرية التي تجري على المتطوعين المرضى منهم أو الأصحاء.

(ب) التجارب الطبية الدوائية غير العلاجية وهي التي تجري على المتطوعين الأصحاء من حيث فاعلية الدواء وحركيته والتوافر والتكافؤ الحيوي للدواء.

(ج) التجارب الطبية الدوائية العلاجية والتجارب الطبية الدوائية غير العلاجية التي تجرى على الحيوان،

الفصل الثاني

شروط وضوابط إجراء التجارب الطبية على الإنسان والحيوان

والجهات التي يسمح فيها بإجراء التجارب الطبية

شروط إجراء التجارب الطبية على الإنسان والحيوان

٥. (١) لا يجوز إجراء التجارب الطبية إلا بعد الحصول على موافقة اللجنة على الطلبات المقدمة من أشخاص مؤهلين بعد موافقة الجهات أو المؤسسات المسئولة عن البحث .

(٢) على الباحث تقديم خطة للدراسة تعتمد من قبل اللجنة على أن تتضمن المسوغات الخاصة بإجراء التجارب الطبية على الإنسان والحيوان .

(٣) يقترح الباحث فريق بحث تعتمده اللجنة من أعضاء مؤهلين علمياً تتوافر لديهم الخبرة العلمية لإجراء التجربة وفقاً للمتطلبات الدراسية ويكون رئيس الفريق مسئولاً عن حسن التنفيذ لهذه الدراسة ،

(٤) يجب تأمين وجود طبيب بشري او طبيب بيطري يقدم الرعاية الطبية أثناء التجربة الطبية على الإنسان والحيوان،

(٥) لايجوز إجراء التجارب الطبية على الحيوان الا بعد الحصول على موافقة الجهة المختصة في حال وجودها.

(٦) لإجراء التجارب الطبية على الدواء أو المستحضر الصيدلاني المسجل لإستخدام مختلف عن الإستخدام المقدم من قبل الباحث، تشترط الموافقة المسبقة من المجلس بناءاً على توصية اللجنة.

ضوابط إجراء التجارب الطبية على الإنسان والحيوان

٦. تمنح الموافقة على إجراء التجارب الطبية على الإنسان والحيوان وفقاً للضوابط الآتية :-

(١) التأكد من كفاءة فريق البحث وقدرته على إجراء الدراسة والتزامه بأسس الممارسة الجيدة لإجراء التجارب الطبية على الإنسان والحيوان.

(٢) إعتماد خطة الدراسة بعد تقييمها والتحقق من صحة المعلومات الواردة فيها والموافقة على بدء إجرائها ومتابعتها.

(٣) يقدم الباحث تقارير دورية للجنة وعليه إخطارها بأي نتائج سلبية غير معروفة عن الدواء تظهر أثناء التجربة الدوائية أو بعدها .

(٤) يجب على الباحث إيداع نسخة من نتائج البحث لدى مقرر اللجنة حال إنتهاء التجربة .

(٥) التأكد من توافق إجراءات التجربة الطبية مع أخلاقيات البحوث والتجارب والدراسات العلمية إقليمياً ووطنياً ودولياً ومتابعة الإلتزام بها .

الجهات التي يسمح فيها بإجراء التجارب الطبية على الإنسان والحيوان

٧. يسمح للجهات الآتية إجراء التجارب الطبية على الإنسان والحيوان وهي :-

(١) الجامعات والمؤسسات الأكاديمية ومؤسسات البحث العلمي المتخصصة وشركات إنتاج الأدوية على أن تتوفر لديها امكانات اجراء التجارب. ويجوز لأي من هذه الجهات إجراء الجانب السريري للدراسة في المستشفيات العامة والخاصة والمراكز العلاجية المتخصصة المرخصة التي تتوافر لديها الإمكانات الفنية للقيام بالعناية الطارئة والحثيثة والفحوصات المخبرية والسريرية اللازمة لإجراء التجارب فيها .

(٢) تجرى التحاليل على العينات الحيوية الخاصة بالتجارب الدوائية في مختبرات معتمدة لدى المجلس تتوافر فيها المتطلبات الضرورية لإجراء التحاليل وضمان جودتها ودقتها .

الفصل الثالث

متطلبات إجراء التجارب الطبية غير العلاجية على الإنسان والحيوان

وضوابط التجارب الطبية الدوائية السريرية (العلاجية) على الإنسان والحيوان

متطلبات إجراء التجارب الطبية غير العلاجية على الإنسان والحيوان

٨. (١) لإجراء التجارب الطبية غير العلاجية على الإنسان والحيوان يجب تقديم طلب رسمي من الجهة طالبة الإجراء وترفق معه دراسة علمية توضح جميع تفاصيل التجربة .

(٢) لإجراء التجارب المعيارية أو التكافؤ الحيوي للأدوية يشترط الآتي :-

جمهورية السودان وزارة الصحة الاتحادية الأمانة العامة المجلس القومي للأدوية والسموم

(أ) بيانات الدواء أو المستحضر الصيدلاني الذي سيتم تجربته وإعطاءه للإنسان والحيوان وجرعاته وكمياته وكيفية تعاطيه ونوع وعدد الفحوصات والتحاليل التي ستجرى على الإنسان أو الحيوان.

(ب) تحديد مكونات الدواء أو المستحضر الصيدلاني وسمياته وتأثيره الحيوي والسريري على الجسم وما يتعلق بمفعوله وآثاره وسلامته على الإنسان والحيوان.

(ج) إرفاق شهادة تسجيل الدواء أو المستحضر من بلد المنشأ .

ضوابط التجارب الطبية الدوائية السريرية (العلاجية) على الإنسان والحيوان

٩. (١) لإجراء التجارب الطبية الدوائية السريرية العلاجية يجب إتباع الضوابط الآتية :-

(أ) على اللجنة القيام بتقييم الدراسة والتحقق من صحة المعلومات المقدمة في الوثيقة العلمية.

(ب) تعتمد اللجنة خطة الدراسة والموافقة على بدء إجرائها ومتابعتها.

(ج) على اللجنة التأكد من كفاءة فريق البحث وقدرته على إجراء الدراسة والتزامه بأسس الممارسة الجيدة المعلومة لإجراء التجارب الدوائية على الإنسان والحيوان.

(د) على الباحث أن يقدم تقارير دورية للجنة والإعلام عن أي نتائج سلبية غير معروفة عن الدواء تظهر أثناء التجربة الدوائية أو بعدها.

(و) على اللجنة متابعة توافق إجراءات التجربة الطبية مع أخلاقيات البحوث والتجارب والدراسات العلمية إقليمياً،وطنياً و دولياً ومتابعة الإلتزام بها.

(٢) على الباحث تقديم نتائج الدراسة قبل السريرية على أن تظهر الآتي:-

(أ) أن تكون فكرة البحث مفيدة.

(ب) الآثار الجانبية والسمية.

(ج) مقدار الجرعات السريرية من المستحضر.

(د) سلامة الأعضاء الرئيسية.

(هـ) حركية الدواء من حيث الإمتصاص والإنتشار والإستقلاب والتخلص.

(٣) على اللجنة التأكد من أن تكون التجربة السريرية ذات فائدة صحية على الإنسان والحيوان وذات مسوغات كافية لإجرائها .

(٤) في حال التجارب السريرية على الإنسان يجب على الباحث التقيد بالممارسات السريرية المعتمدة.

(٥) في حال إجراء التجارب السريرية على الحيوان يجب على الباحث الإلتزام بأسس الممارسة المعلومة لإجراء التجارب الدوائية على الحيوان وأن تكون التجربة في بيئة صحية تحت إشراف طبيب بيطري.

صدر تحت إسمي وتوقيعي في يوم ١٧ **من شهر** ربيع الأول **لسنة** ١٤٣٩ **الموافق ليوم** ٥ **من شهر** ديسمبر **لسنة** ٢٠١٧

5-12-17

أ. بحر إدريس ابو قردة
وزير الصحة الإتحادي
رئيس المجلس القومي للأدوية والسُموم

وزارة الصحة الاتحادية
Federal Ministry of Health
الوزير
MINISTER

جمهورية السودان
وزارة الصحة الاتحادية
الأمانة العامة
المجلس القومي للأدوية والسموم

5.3 Appendix 3: The SOPs of conducting clinical trials on humans and animals-NMPB

National Medicines and Poisons Board Secretary General Secretariat General of Planning and Policies Studies and Research Department	SOPs for **Approval to Conduct Clinical Trials on Humans and Animals in Sudan**	
Prepared by: **Name:** Dr. Reem Abdulaziz Abdulrahman Hussein **Position:** Member and rapporteur of the committee of conducting clinical trials on humans and animals in Sudan **Signature:** **Date:** 26. 05. 2022	**Checked by:** **Name:** Dr. Wijdan Khalid Mohamed Elfil **Position**: Head of the Secretariat General of Planning and Policies **Signature:** **Date:** 26-5-2022	**Approved by:** **Name: Al-Shima Salah Eldain** **Position**: Head of the Quality Unit **Signature:** AlShaima **Date:** 26.5.2022

A. PURPOSE

To ensure technical and ethical aspects of clinical trials involving therapeutic and non-therapeutic medicinal products and new devices involving humans and animals in Sudan.

B. RESPONSIBILITY

The clinical trials officer is responsible for receiving and checking the submitted documents, thereafter the rapporteur should review the documents and prepare for the committee meeting. Lastly, the committee is responsible for reviewing, then approving or rejecting of clinical trials on humans and animals in Sudan.

C. SCOPE

The scope of the committee involves technical, ethical and scientific aspects of humans and animals in Sudan.

D. FREQUENCY OF MEETINGS

- The meeting of the committee every week and more frequent if necessary.
- All meetings' minutes are documented and saved at least for 5 last years.
- The chairman of the committee has the right to assign responsibilities and duties to any other member in his or her absence.
- For legal meeting, the quorum should be of at least half the number + 1 of the committee's members.

E. PROCEDURE

1. Receiving the document of the project:

1.1. The principal investigator shall submit a project's documents (the proposal) to the NMPB according to the check list form No. **(PSR-F - 03-01).**

1.2. The clinical trials officer should check the submitted documents to ensure that it meets the requirements, then send the clinical trials application forms to the researcher which are **(PSR/F/03/03)**, **(PSR /F/03/04)**, **(PSR/F/03/05)**, **(PSR/F/03/06)**, **(PSR/F/03/07)**, **(PSR /F/03/08)**.

1.3. The principal investigator shall submit the documents of the intended clinical trial as requested and must include forms No. **(PSR /F/03/03)**, **(PSR /F/03/04)** or **(PSR /F/03/08)**, **(PSR/F/03/05)** or **(PSR/F/03/07)** and **(PSR /F/03/06).**

2. Assessment of the completion of the document of the project:

2.1. The clinical trials officer shall review the contents of the project's documents, uncompleted document/s should be returned to the applicant for correction or completion according to the requirements stated No. **(PSR -F- 03-02)**.

2.2. The clinical trials officer shall review the documents within a period not exceeding one week from the date of receiving the document according to the form No. **(PSR -F - 03-02)**.

2.3. After ensuring the completeness of project's documents, it will be submitted to the rapporteur of the committee as soon as possible (Maximum 2 weeks).

3. Review of the document by the committee:

3.1. The document of the clinical trial should be presented to the committee by the rapporteur for review.

3.2. The committee may request more information about the proposed clinical trial or invite the principal investigator to meet the committee when necessary.

3.3. The rapporteur issues a letter to the principal investigator to provide the information needed or meet the committee accordingly.

3.4. The committee may visit the project site before the start of the trial.

3.5. When the final decision is made, the rapporteur of the committee should issue a decision letter signed by the secretary general to the principal investigator or the research sponsoring body.

3.6. The rapporteur of the committee should notify the principal investigator or the body sponsoring the research to receive the committee decision letter.

3.7. In case of approval of the clinical trial the researcher receives an ethical clearance certificate.

4. Reporting and Follow-up:

4.1. The committee may visit the project site during the progress of the clinical trial as deemed appropriate by the committee.

4.2. In multi center trials or large studies, the committee may require a Data and Safety Monitoring Board DSMB to be formed to keep the Committee up to date regarding the balance between risks and benefits.

4.3. The committee should receive progress reports at least every 6 months and the final report after completion of the project.

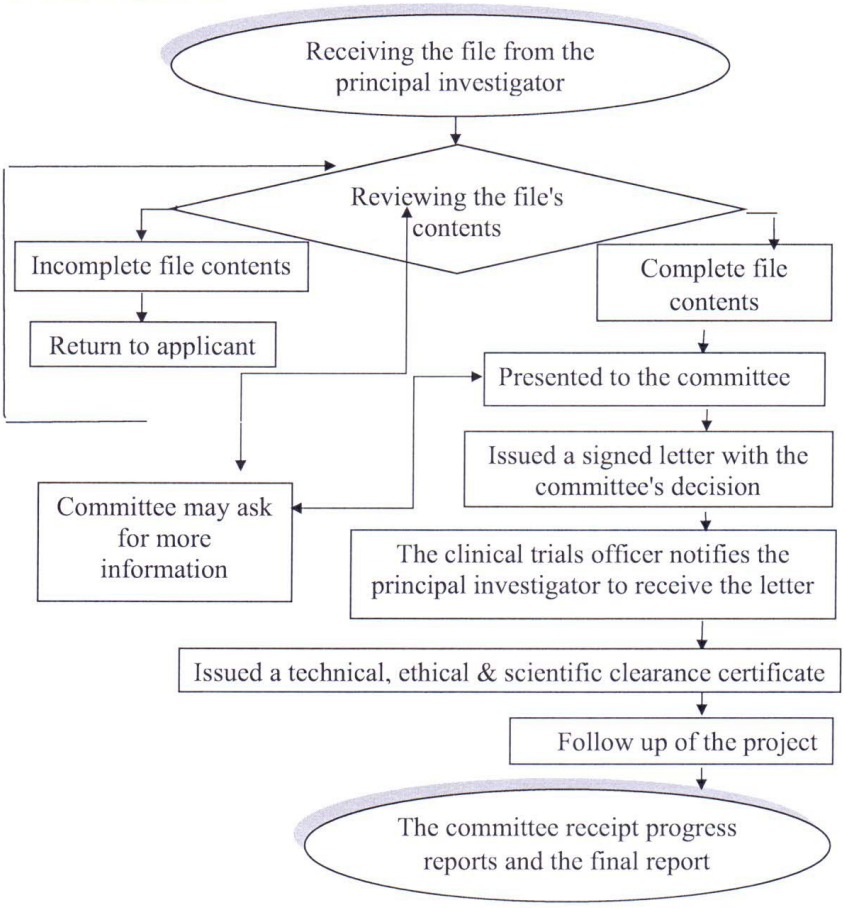
F. REFERENCE

- The guideline of conducting clinical trials on humans and animals.
- Medicines and Poisons Act 2009.
- Good Clinical Practice E6(R2).

G. ATTACHEMENT

1. PSR -F - 03-01
2. PSR -F - 03-02
3. PSR -F - 03-03
4. PSR -F - 03-04
5. PSR -F - 03-05
6. PSR -F - 03-06
7. PSR -F - 03-07
8. PSR -F - 03-08

H. FLOW CHART


Receiving the file from the principal investigator
Reviewing the file's contents
Incomplete file contents
Return to applicant
Committee may ask for more information
Complete file contents
Presented to the committee
Issued a signed letter with the committee's decision
The clinical trials officer notifies the principal investigator to receive the letter
Issued a technical, ethical & scientific clearance certificate
Follow up of the project
The committee receipt progress reports and the final report

I. REVISION FOLLOW UP

No.	Date	Revision	Responsible person	Page No	Comment