ETHIOPIAN FOOD AND DRUG AUTHORITY

የህክምና ሙከራ መመሪያ ቁጥር 964/2015

CLINICAL TRIAL DIRECTIVE No. 964/2023

ሚያዝያ, 2015

April, 2023

DIRECTIVE NO. 964/2023	መመሪያ ቁጥር 964/2015
WHEREAS standardization and harmonization are necessary for clinical trial applications, protocol, and compilation of essential documents that include results of tests and clinical trials carried out on the product as well as their presentation for clinical trial authorization;	የህክምና ሙከራ ለማከናወን የሚቀርቡ ማመልከቻዎች፣ ፕሮቶኮል፣ እና ከህክምና ሙከራ ጋር ተያያዥነት ያላቸው ሰነዶችን፣ በሰነዶች ውስጥ የሚካተቱ የህክምና ሙከራው ውጤቶች ፣ ሙከራው የሚደረግበት መድሓኒት መረጃዎች ተጠናቅረው የሚቀርቡበት ደረጃ የተቀናጀ አና ወጥነት ያለው እንዲሆን በማስፈለጉ፤
WHEREAS ensuring trial participants' rights, safety, and well-being are protected, clinical-trial data are credible, and unnecessary clinical trial-related activities will not be conducted; it is critical to state principles of good clinical practice while allowing the results of the trials to be documented for use in a later phase;	የህክምና ሙከራ ላይ የሚሳተፉ ሰዎች ደህንነት እና መብት እንዲጠበቅ፤ የህክምና ሙከራ መረጃዎች ተዓማኒ እንዲሆኑ እና አላስፈላጊ ከህክምና ሙከራ ጋር የተገናኙ ተግባራት እንዳይከናወኑ ለመከላከል፤የመልካም ህክምና ሙከራ ስርዓት መርሆዎችን በማስቀመጥ ከህክምና ሙከራ የተገኙ ውጤቶች ለቀጣይ ደረጃ ጥቅም ላይ እንዲውሉ ማድረግ በማስፈለጉ፤
WHEREAS, as expressed in the 1964 Helsinki Declaration, the acknowledged basis for the conduct of clinical trials in humans is predicated on the preservation of human rights, the dignity of the human person, and the clinical trial participant's protection concerning the application of investigational product, diagnostic or medical procedure;	እ.ኤ.አ. በ 1964 በጸደቀዉ የሄልሲንኪ ድንጋጌ ላይ እንደተገለጸው ፣ በሰዎች ላይ የሚከናወን የህክምና ሙከራ ተቀባይነት የሚኖረው የተሳታፊዎቹን ሰብአዊ መብቶች፣ የሰውን ልጅ ክብር እና ለሙከራ ከሚሰጠው መድሃኒት ጋር ተያይዞ ተሳታፊዎቹን ደህንነት መጠበቅን መሰረት ያደረገ መሆን ስለሚገባው፤

WHEREAS, it is required to set appropriate administrative measures in cases of any violations of legal requirements, appropriate rules and laws in conducting clinical trials	የህክምና ሙከራዎችን በሚደረጉበት ጊዜ አግባብ ያላቸዉን የሕግ መርሆችን እና ድንጋጌዎችን ከተጣሱ ተገቢውን አስተዳደራዊ እርምጃ መዉሰድ በማስፈለጉ።
NOW, THEREFORE, this directive is issued under article 71 sub-article 2 of the Ethiopian Food and Medicine Administration Proclamation no 1112/2019.	በምግብ እና መድኃኒት አስተዳደር አዋጅ ቁጥር 1112/2011 አንቀጽ 71 ንዑስ አንቀጽ (2) መሰረት ይህ መመሪያ ወጥቷል፡፡
CHAPTER ONE	ምእራፍ አንድ
GENERAL PROVISIONS	አጠቃላይ ድንጋጌዎች
1. Short Title	1. አጭር ርዕስ
This directive may be cited as ``Clinical Trial Directive No 964/2023 ``	ይህ መመሪያ “የህክምና ሙከራ መመሪያ ቁጥር 964/2015” ተብሎ ሊጠቀስ ይችላል፡፡
2. Definitions	2. ትርጓሜ
Unless otherwise a different meaning is given , in this directive	የቃሉ አገባብ ሌላ ትርጉም የሚያሰጠው ካልሆነ በስተቀር በዚህ መመሪያ ውስጥ፡
1) **“A bioavailability study”** is a pharmacokinetic study that demonstrates the rate and extent to which the active ingredient is absorbed from a drug product and becomes available at the site of action.	1) **"የባዮአቫይለቢሊቲ ጥናት"** ማለት የፋርማኮካይነቲክ ጥናት ሲሆን የመድኃኒቱ ዋና ንጥረ ነገር ወደ ሰውነት ገብቶ የመድኃኒቱ ውጤት በሚፈለግበት ቦታ የሚደርስበትን ፍጥነት እና መጠን የሚያሳይ ጥናት ነው።
2) “**A bioequivalence study**” is a special	2)**“የባዮኢኩቫለንስ ጥናት”** ሁለት የተለያዩ

study where two drugs or two sets of formulations of the same drug are compared to show that they have nearly equal bioavailability and Pharmacokinetic/Pharmacodynamics parameters.	መድኃኒቶች ወይም በተለያየ መልክ የተዘጋጁ አንድ አይነት መድኃኒቶች ሲነፃፀሩ ከሞላ ጎደል ተመሳሳይ የባዮአቪለቢሊቲ እና ፋርማኮኪኔቲክ/ፋርማኮዳይናሚክ ውጤት እንዳላቸው የሚያሳይ ልዩ ጥናት ነው።
3) "Adverse Drug Event" means any un toward medical occurrence that may be present during treatment with a medicine but doesnot necessarily have a causal relationship with this treatment, that is, an adverse out come that occurs while the patientis taking themedicine but is not, or not necessarily, attributable to it.	3) **"የመድኃኒት ጎጂ ክስተት"** ማለት ማንኛውም ሰው መድኃኒት ከወሰደ በኋላ የሚከሰት የሚጠበቅ ወይም ያልተጠበቀ አለታዊ ክስተት ሲሆን ክስተቱ የመጣው በመድኃኒቱ ምክንያት ወይም ከመድኃኒቱ ውጪ ባለ ሁኔታ ሊሆን ይችላል፤
4) **"Amendment''** means a written description of a change(s) made to a clinical trial after being authorized by the authority.	4) **"ማሻሻያ'** ማለት ከባለስልጣኑ ፍቃድ የተሰጠው የህክምና ሙከራ ላይ የሚደረግ ለውጥ (ጦች) የሚገልጽ የጽሁፍ ማብራሪያ ነው።
5) "**An Independent Ethics Committee"** is research ethics review body established under a relevant government body and mandated to conduct ethical reviews.	5) **"ገለልተኛ የስነምግባር ኮሚቴ"** ማለት የምርምር ስነምግባር አካል ሆኖ በሚመለከተው የመንግስት አካል ስር የተቋቋመና የስነምግባር ግምገማ ለማድረግ ኃላፊነት ያለዉ ነዉ።
6) **"Applicable Regulatory Requirement''** means any law, regulation or directives addressing the conduct of clinical trials on human participant.	6) **"ተፈፃሚነት ያላቸው የቁጥጥር መስፈርቶች"** ማለት በሰው ላይ የሚደረጉ የህክምና ሙከራዎችን የሚመለከት ማንኛውም ህግ ፣ ደንብ ወይም መመሪያ ነው።

7) **“Assent’’** means the agreement to participate in research by persons who are in the age of 12-17 years and too young to give informed consent but who are old enough to understand the proposed research.	**“ለአካለ መጠን ያልደረሱ ተሳታፊነት ስምምነት”** ማለት ከ 12-17 አመት የእድሜ ክልል ውስጥ የሚገኙ በመረጃ ላይ የተመሰረተ ስምምነት ለመስጠት በእድሜ ትንሽ የሆኑ ነገር ግን የታቀደውን ጥናት መረዳት የሚችሉ ሰዎች በህክምና ሙከራ ውስጥ ለመሳተፍ ፈቃድ የሚሰጡበት ስምምነት ነው፡፡
7. “Audit`` means a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted and whether the data were recorded, analyzed, and accurately reported according to the protocol, standard operating procedures, Good Clinical Practice (GCP), and the applicable regulatory requirement;	8) **"ኦዲት"** ማለት ከህክምና ሙከራ ጋር የተገናኙ ተግባራትን እና ሰነዶችን ገለልተኛ በሆነ መልኩ በመመርመር፣ የህክምና ሙከራዉ ተግባራት የተከናወኑት በፕሮቶኮል፣ በአሰራር መመሪያ መሰረት መሆኑን ፣ መልካም የህክምና ሙከራ ስርአት እና አስፈላጊ የቁጥጥር መስፈርቶች መተግበራቸውን ማረጋገጥ ነው ።
8. “Authority” means the Ethiopian Food and Drug Authority;	9) **“ባለሥልጣን”** ማለት የኢትዮጵያ የምግብና መድኃኒት ባለሥልጣን ነው፤
9. “Biological products” means diverse group of medicines which includes products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues and recombinant therapeutic proteins.	10. **"ባዮሎጂካል ምርቶች"** ማለት የተለያዩ የመድኃኒት ስብስቦችን ያካተተ ሲሆን እንደ ክትባት፣ ደም እና የደም ተዋፅኦ፣ አለርጂኖች፣ የሶማቲክ ሴሎች፣ የዘረመል ህክምና፣ ህብረህዋሶች እና በዘረመል ጥምረት የሚገኙ የፕሮቲን ህክምናዎች ያጠቃልላል፡፡
10. “Blinding” is a procedure in which one or more parties to the trial are unaware of the	11) **“የጥናትን አካሄድ አለማሳወቅ”** ማለት በህክምና ሙከራ ከሚሳተፉ አካላት ውስጥ

treatment assignment(s).	አንድ ወይም ከዚያ በላይ የሆኑት አካላት የትኛው ዓይነት የህክምና ምርት ለየትኛው የጥናት ተሳታፊ እንደተሰጠ እንዳይታወቅ የሚደረግበት ሂደት ነው፡፡
11. "Case Report Form'' means a printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial participant;	12) **"የህክምና ሪፖርት ማቅረቢያ ቅጽ"** ማለት የታተመ ወይም የኤሌክትሮኒክስ ሰነድ ሲሆን ስለ እያንዳንዱ የህክምና ሙከራ ተሳታፊ በተመለከተ በፕሮቶኮሉ የተቀመጡ ተፈላጊ መረጃዎች የሚመዘገብበት እና ለስፖንሰር የሚቀርብበት ቅፅ ነው።
12. "Clinical Trial Report'' means a written description of a detailed report of an authorized clinical trial conducted on human subjects, in which the clinical description, presentations, and analyses are fully integrated into a single report;	13) **"የህክምና ሙከራ ሪፖርት"** ማለት ፈቃድ የተሰጠው በሰዎች ላይ የተካሄደ የህክምና ሙከራ የጽሑፍ መግለጫ ሲሆን ፣ የህክምና ዘገባው ፣ አቀራረቡ እና ትንታኔዎች በአንድ ሪፖርት ውስጥ ተካተው የሚቀርቡ ናቸው ።
13. "**Clinical trial"** means any systematic study on investigational products, diagnostic or medical procedures in volunteer human participants in order to discover or verify the effects of, and/or identify any adverse reaction to the products, and or to study its absorption, distribution, metabolism, and excretion with the object of ascertaining their efficacy and safety;	14. **"የህክምና ሙከራ"** ማለት በመድኃኒቶች፣ ባዮሎጂካዊ ምርቶች ፣ ክትባቶች ወይም የሕክምና ሂደቶችን ጨምሮ ፈቃደኛ በሆኑ ተሳታፊዎች ላይ የሚከናወን ጥናት ሆኖ የሚያስከትለውን ውጤት እና/ወይም የሚያመጣውን ጎጂ ባህሪ ለመለየት እንዲሁም የመድሃኒቱን ከሰውነት ጋር ያለውን መስተጋብር በማጥናት ፈዋሽነቱን እና ደህንነቱን ለማረጋገጥ የሚደረግ ጥናት ነው።
14. "Clinical Trial Study Team'' means physical persons who work within the trial sites to deliver high-quality clinical trials	15) **"የህክምና ሙከራ ቡድን"** ማለት የህክምና ሙከራው በሚከናወንበት ቦታ በአካል በመገኘት ሙከራው በከፍተኛ ጥራት

in a safe environment and may be composed of a Site Principal Investigator, co-investigators, Biostatistician, Study Coordinator, Nurse, Data Manager, Pharmacist, etc.;	ደህንነቱ በተጠበቀ ሁኔታ እንዲከናወን የሚሰሩ አካላት ሲሆኑ ይህም የሳይት ዋና ተመራማሪ፣ ምክትል ተመራማሪዎች፣ ባዮስታቲስቲክስ ባለሙያ፣ የጥናት አስተባባሪ፣ የሙከራ ነርስ፣ የህክምና ሙከራ ፋርማሲስት ሊሆኑ ይችላሉ።
15. "Sub-Investigator'' means an individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions; including assuming Investigator responsibilities in his/ her absence.	16) **"ረዳት ተመራማሪ"** ማለት የህክምና ሙከራ ቡድን አባል የሆነ ግለሰብ ሆኖ በዋናዉ ተመራማሪ ተሰይሞ ክትትል አየተደረገለት በህክምና ሙከራዉ ተቋም ወሳኝ የሆኑ የህክምና ሙከራ ስራዎችን የሚያከናውን ፣አስፈላጊ የህክምና ሙከራ ዉሳኔዎችን የሚያስተላልፍ እንዲሁም ዋናዉ ተመራማሪ በማይኖርበት ወቅት የርሱን ሃላፊነት የሚተካ ነው።
16. ''Compassionate use'' means a way to provide an investigational therapy to a patient who is not eligible to receive that therapy in a clinical trial, but who has a serious or life-threatening illness for which other treatments are not available.	16) **"የህክምና ሙከራ የሚደረግበትን ምርት ለመደበኛ ህክምና ስለመጠቀም"** ማለት በህክምና ሙከራ ውስጥ ለመሳተፍ መስፈርቱን ለማያሟላ፣ ነገር ግን ከባድ ወይም ለሕይወት አስጊ ህመም ላለባቸው እና ሌላ የሕክምና አማራጭ ለሌላቸው ታካሚዎች የህክምና ሙከራ ምርት እንዲጠቀሙ የሚፈቀድበት መንገድ ነው።
17. "Consent" means a process by which a participant voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate.	17) **"ስምምነት"** ማለት የህክምና ሙከራ ተሳታፊው ከህክምና ሙከራው ጋር ተያያዥነት ያላቸውን ሁሉም መረጃዎች ከተገለጸለት በኋላ በአንድ የህክምና ሙከራ ውስጥ ለመሳተፍ ፈቃደኛ መሆኑን

Informed consent is documented by means of a written, signed and dated informed consent form.	የሚያረጋግጥበት ሂደት ነው። ስምምነቱ በተጸፈ፣ በተፈረመ፣ እና ቀን ባለው የስምምነት ቅጽ አማካይነት ይሰነዳል።
18. "Contract Research Organization'' means a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions;	18) **"የኮንትራት ጥናት ድርጅት"** ማለት ከህክምና ሙከራ ጋር የተያያዙ ተግባራትን ለማከናወን በስፖንሰር አድራጊው ውክልና የተሰጠው ሰው ወይም ድርጅት (የንግድ፣ የትምህርት ተቋም ወይም በሌላ ዘርፍ) ነው፤
19. "Country Principal Investigator'' means a person resident in Ethiopia, responsible for the conduct of the clinical trial in the country which shall be a medical practitioner or other qualified health care professionals and responsible for leading and coordinating the clinical trials at the multiple sites.	19. **"በሀገር ውስጥ የሚገኝ ዋና ተመራማሪ"** ማለት በኢትዮጵያ ነዋሪ የሆነ፣ በሀገሪቱ ውስጥ ለሚደረገው የህክምና ሙከራ ኃላፊነት የተሰጠው የህክምና ባለሙያ ወይም ሌላ ብቁ የጤና ባለሙያ ሆኖ በተለያዩ ቦታዎች የሚካሂዱ የህክምና ሙከራዎችን የመምራት እና የማስተባበር ኃላፊነት ያለበት ነው።
20. ''Critical finding'' means evidences that the Participant's/patient's right, safety and/or confidentiality either have been or have significant potential to be compromised or serious doubts about the accuracy and/or credibility of data.	20) **"ወሳኝ ግኝት"** ማለት የህክምና ሙከራ ተሳታፊው/የታካሚው መብት፣ደህንነት እና/ወይም ምስጢራዊነት ያለመጠበቅ ሁኔታ እንደነበረው ወይም እንዳለ እንዲሁም ስለመረጃ ትክክለኛነት እና/ወይም ተአማኒነት ከፍተኛ ጥርጣሬዎች እንዳለ የሚያሳይ ማስረጃ ነው።
21. "Data and Safety Monitoring Board'' means an independent data-monitoring committee that maybe established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the	21) **"የመረጃ እና ደህንነት ክትትል ቦርድ"** ማለት በስፖንሰር አድራጊው የሚቋቋም ራሱን የቻለ የመረጃ ደህንነት የሚከታተል ኮሚቴ ሲሆን በየተወሰነ ጊዜ የህክምና ሙከራ

critical efficacy endpoints and to recommend to the sponsor whether to continue, modify, or stop a trial;	ሂደቱን፣ የደህንነት መረጃን እና ወሳኝ የውጤት ነጥቦችን በመከታተል የህክምና ሙከራውን ለማስቀጠል፣ ለማሻሻል ወይም ለማስቆም ለስፖንሰሩ ሀሳብ የሚያቀርብ ነው።
22. "**Documentation "**means all records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken;	22) **"ሰነድ"** ማለት የህክምና ሙከራ የሚካሄድበት አሰራሮች ፣ የምርምር ውጤቶች፣ በሙከራው ላይ ተጽእኖ የሚያሳድሩ ሁኔታዎች እና የተወሰዱ ርምጃዎችን የሚገልጹ ወይም በማንኛውም መልኩ የሚመዘግቡ (በጽሑፍ ፣ ኤሌክትሮኒክ ፣ ማግኔቲክ እና ኦፕቲካል መዛግብት ፣ እና ስካን ፣ ኤክስሬይ እና ኤሌክትሮካርዲዮግራም ጨምሮ) ማለት ነው ።
23. ''Essential Documents'' means documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.	23) **"አስፈላጊ ሰነዶች"** ማለት በግል እና በቡድን የህክምና ሙከራ ሂደትን እና የሚገኘውን መረጃ ጥራት ለመገምገም የሚፈቅዱ ሰነዶች ማለት ነው። እነዚህ ሰነዶች የተመራማሪውን፣ የስፖንሰሩን የመልካም የህክምና ሙከራ ሂደት እና ተግባራዊ የቁጥጥር መስፈርቶችን መከተላቸውን ለማሳየት የሚያገለግሉ ሰነዶች ናቸው።
24. "Expedite review" means reviewing and approving clinical trials following a fast-track or non-routine procedure during public health emergencies, addressing public health interest, or where access to new therapies needs to be made faster	24) **"የተፋጠነ ግምገማ"** ማለት በሕዝብ ጤና ድንገተኛ አደጋዎች ወቅት ፈጣን ወይም መደበኛ ያልሆነ አሰራርን በመከተል የህክምና ሙከራዎችን መገምገም እና ፍቃድ መስጠት፣ የህዝብ ጤና ፍላጎትን ማማላት፣ ወይም አዳዲስ የሕክምና መፍትሄዎችን

than the routine timelines to save or dramatically improve patients' lives are necessary.	ለማግኘት ከመደበኛ የግምገማ የጊዜ ሰሌዳ በበለጠ ፍጥነት ሙከራውን መፍቀድ ነው።.
25. "Good Clinical Practice'' means an international ethical and scientific standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that assures that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected.	25) **"መልካም የህክምና ሙከራ ስርዓት"** ማለት አለም አቀፍ የስነ-ምግባር እና ሳይንሳዊ ደረጃዎችን በመጠቀም የህክምና ሙከራ አሰራሮችን በመቅረፅ፣ ሂደቱን በመከታተል፣ ኦዲት፣ መረጃ በመመዝገብ፣ በመተንተን፣ ሪፖርት በማድረግ የተገኘው መረጃ ትክክለኛ እና ታማኝነት ያለው መሆኑን፣ በህክምና ሙከራው የሚሳተፉ ሰዎች መብት መጠበቁን ማረጋገጥ ነው።
26. "Independent Ethics Committee" means an independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of health professionals and non-medical members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the trial protocol, the suitability of the investigator (s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial	26) **"ገለልተኛ የምርምር ስነምግባር ኮሚቴ ማለት"** ገለልተኛ አካል (ግምገማ ቦርድ ወይም ኮሚቴ፣ ተቋማዊ፣ክልላዊ፣ ሀገር አቀፋዊ፣ ቀጠናዊ) ሲሆን በዉስጡ የህክምና ባለሙያዎችንና የህክምና ባለሙያ ካልሆኑት አባላት ተቋቁሞ የህክምና ሙከራ ተሳታፊዎችን መብት፣ደህንነትና አጠቃላይ ጤና ለማረጋገጥ ኃላፊነት ይህም የህብረተሰብ ጥበቃ ለማረጋገጥና ከሌሎች ስራዎች በተጨማሪ የህክምና ሙከራ ፕሮቶኮል ግምገማ፤ የተመራማሪዎችን፤ የተቋሙን ግብዓቶች ፣ይጥናቱ አደራረግ ዘዴዎች አግባባዊነት(ተክክለኛነት)ና የተሳታፊዉን ተሳትፎ ስምምነት ፈቃድ ለመዉሰድ የተዘጋጁ ፎርሞችና መረጃ መስጫ ጽሁፎችን

participants;	በመገምገምና ለማጽደቅ ወይም ጥናቱ እንዲቀጥል የተሰጠ አስተያየት
27. "Inspection" means the act of a regulatory authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organizations (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority.	27) "**ቁጥጥር**" ማለት ከህክምና ሙከራ ጋር ግንኙነት አላቸው ተብለው የሚታሰቡት ሰነዶች፣ ተቋማት፣ መዝገቦች እና ሌሎች መረጃዎች ላይ በተቆጣጣሪ አካላት በኩል የሚደረግ የግምገማ ስራ ሲሆን የተጠቀሱት ሰነዶች የህክምና ሙከራው በሚከናወንበት ቦታ፣ ስፖንሰሩ ጋር እና/ወይም የኮንትራት ምርምር ድርጅቶች እንዲሁም ሌሎች በተቆጣጣሪ አካላት ብቁ ተብለው በሚታሰቡ ተቋማት ውስጥ ሊቀመጡ ይችላሉ።
28. "Investigational Product'' means a pharmaceutical form of an active ingredient or placebo, biologicals including vaccines being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form or when used for an unapproved indication, or when used to gain further information about an approved use;	28) **"የምርምር ምርት"** ማለት በገበያ ላይ ከዋለ ምርት ጋር ሲዋሃድ ወይም ሲቀናጅ የገበያ ፈቃድ የሚያገኝ ምርትን ወይም በጥቅም ላይ ስለዋለ ምርት ተጨማሪ መረጃ ለማግኘት አላማ የሚዉል ምርት ወይም ለንጽጽርነት የሚያገለግል ምርትን ጨምሮ ለህክምና ሙከራ አገልግሎት የተመረተ ለመድሃኒትነት የታለመ ንጥረነገር ነዉ።
29. "**Investigator's Brochure"** means a collection of data consisting of all the information known before the trial concerning the clinical and non-clinical	29) **"የተመራማሪ ማስታወሻ"** ማለት የህክምና ሙከራ ሰለሚደረግበት ምርት ከህክምና ሙከራ በፊት የተሰበሰበ የህክምናና የቅድመ ህክምና ሙከራ አጠቃላይ መረጃ ነዉ::

data on the investigational product;	
30. ‘‘Major amendments’’ means amendments to the trial where they are likely to have a significant impact on the safety or physical or mental integrity of the participants; the scientific value of the trial; the conduct or management of the trial; or the quality or safety of any investigational product used in the trial.	30)**“ዋና ማሻሻያዎች”** የህክምና ሙከራ ላይ የተደረጉ ማሻሻያዎች ሲሆኑ በተሳታፊዎች ደህንነት ወይም አካላዊ ወይም አእምሯዊ ጤና ፤ የሙከራው ሳይንሳዊ ይዘት; አጠቃላይ የሙከራዉ አደራረግ ሂደት ; ወይም ለሙከራው ጥቅም ላይ በዋለው ማንኛውም የምርምር ምርት ጥራት ወይም ደህንነት ላይ ከፍተኛ ተጽዕኖ ሊያሳድሩ ይችላሉ፤
31) **‘‘Major finding’’** means a major non-compliance with applicable regulations and guidelines that may not have developed into a critical issue, but which may have the potential to do so unless addressed. Numerous minor non-compliances within one system may also result in a major finding.	31.**“መካከለኛ ግኝት”** ማለት ከሚመለከታቸዉ የህግ መስፈርቶች ወይም መመሪያዎች ጋር የተጣረሰ የምርምር አካሄድ ሲሆን ። በአንድ ስርዓት ውስጥ ያሉ በርካታ ጥቃቅን አለመታዘዝ ትልቅ ግኝትንም ሊያስከትሉ ይችላሉ።ይህም ከፍተኛ ወደ ሆነዉ ግኝት ሊያድግ የማይችል ነገር ግን ማስተካከያ እርምጃ ካለተወሰደ ከፍተኛ ግኝት ሊያድግ ይችላል፡፡ በአንድ ሙከራ አደራረግ ሊኖሩ የሚችሉ ብዙ ዝቅጠኛ ግኝቶች ወደ መካከለኛ ግኝቶች ሊያድጉ ይችላሉ፡፡
32) “**Minors**’’ means a natural person under 18 years of age;	32. **“ለአካለ መጠን ያልደረሰ”** ማለት 18 ዓመት በታች የሆነ የተፈጥሮ ሰዉ ነዉ።
33) **‘‘Minor Amendment’’** means amendment to the trial where they do not involve a more than minimum risk for participants or the conduct of the trial and do not have significant impact on the scientific	33.**«አነስተኛ ማሻሻያ”** ማለት ለተሳታፊዎች ወይም ለሙከራው አፈጻጸም ከዝቅተኛ አደጋ በላይ የማያስከትሉና በሙከራው ሳይንሳዊ ጠቀሜታ ላይ ፤ አጠቃላይ የሙከራዉ አደራረግ ሂደት ላይ ፤ ወይም ለሙከራዉ ጥቅም ላይ የዋለውን

value of the trial; the conduct or management of the trial or safety of investigational product used in the trial.	የምርምር ምርት ደህንነት ላይ ከፍተኛ ተጽኖ የማይፈጥር ነነዉ፡፡
34) **‘‘Monitor’’** means a person appointed by the sponsor or Contract Research Organization (CRO), and responsible to the sponsor or CRO, for the monitoring and reporting of progress of the trial and for verification of data.	34."**የክትትል ባለሙያ**" ማለት በስፖንሰር ወይም በኮንትራት ምርምር ድርጅት የተሰየም ሲሆን ለስፖንሰር ወይም ለኮንትራት ምርምር ድርጅት, ለሙከራ ሂደት በመከታተልና የህክምና ሙከራ የደረሰብትን ደረጃ ሪፖርት የሚያደርግና እና መረጃን የማረጋገጥ ኃላፊነት ያለው ግለሰብ ነዉ፡፡
35) **‘‘Monitoring’’** means the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).	35. "**ክትትል**"' ማለት የህክምና ሙከራ የህክምና ሙከራን ፕሮቶኮል፣ ስታንዳርዶችን፣ መልካም የህክምና ሙከራ ስርዓትንና የሚመለከተው የቁጥጥር መስፈርቶች መሰረት መካሄዱን፤ መረጃዎችን መያዛቸዉንና ሪፖርት አደራረጋቸዉን የማረጋገጥና የመቆጣጠር ተግባር ነው።
36) “**Multi-center clinical trial** “means a clinical trial conducted according to a single protocol but at more than one site, and therefore by more than one investigator;	36. **“ባለብዙ ማዕከል የህክምና ሙከራ**” ማለት በአንድ ፕሮቶኮል ነገር ግን ከአንድ በላይ በሆኑ ተቋማት ከአንድ በላይ በሆኑ ተመራማሪዎች የሚደረግ የህክምና ሙከራ ነዉ፡፡
37) **“Multicounty clinical trial”** means a clinical trial conducted in more than one country.	37.**“ባለብዙ ሀገሮች የህክምና ሙከራ”** ማለት ከአንድ በላይ በሆኑ ሀገሮች የሚደረግ የህክምና ሙከራ ማለት ነዉ፡፡
38) **‘‘Other (Minor) finding’’** A minor non-compliance with applicable regulations and guidelines that need to be addressed in order to have sustained confidence in the work of the organization.	38.**“ሌላ (ጥቃቅን) ግኝቶች”** ማለት ተፈፃሚ መሆን የሚገባቸው ደንቦች እና መመሪያዎችን ባለመከተል ምክንያት የሚከሰት በተቋም አሰራር ላይ ዘላቂ የሆኑ መተማመንን የሚቀንስ መለስተኛ ግኝት ነው፡፡

39) **“Placebo”** means an inactive treatment, be it in a pill or tablet form, or it may be in any pharmaceutical dosage form and often look like and tastes investigational product that is being studied except with no effect on the disease the new investigational product is intended to treat.	39.“ፕላሴቦ” ማለት በእንክብል ወይም በሌሎች መድኃኒቶች በሚመረቱበት ቅርጽ የህክምና ሙከራ ከሚደረግበት ምርት ጋር የሚመሳሰልና አንድ አይነት በጣዕም ያለዉ ነገርግን በበሽታዉ ላይ ምንም ዓይነት የሚሞከረዉ ምርት ያመጣል ተብሎ የታሰበበትን ለዉጥ ማምጣት የማይችል ምርት ነዉ
40) **“Principal Investigator’’** means a person responsible for conducting the clinical trial at a trial site;	40.“ዋና ተመራማሪ“ በሀገር ዉስጥ የሚኖር የህክምና ሙከራለማካሄድ በተ ተቋምኃላፊነት.ያላወየህክምናባለሙ.ያ፣ የጥርስሃኪምወይምሌላዉአግባቢነትባለዉት ምህርት.ብቁናየህክምናሙከራፕሮቶኮልዉስ ጥየተጠቀሰዉንቡድንየመምራትኃላፊነት.ያለ ዉሰዉነዉ
41) **‘‘Protocol Deviation’’** means accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. Deviations may result from the action of the subject, researcher, or research staff.	41.«ፕሮቶኮል መዛባት” ማለት በአጋጣሚ ወይም ሳይፈለግ ያለ ስነምግባር ኮሚቴ ወይም ሰፖንሰር ፈቃድ የተደረገ ለዉጥ ወይም በስነምግባር ኮሚቴ የጸደቀውን ፕሮቶኮል ያለቅድመ ስፖንሰር ወይም የምርምር ስነግባር ኮሜቴ ፈቃድ አለመከተል ማለት ነው። የፕሮቶኮል መዛባት በአጠቃላይ ስጋትን አይጨምርም ወይም ጥቅምን አይቀንሱም፣ የተሣታፊውን መብቶችና ደኅንነት ወይም በመረጃው ትክክለኛነት ላይ ትርጉም ያለዉን ተጽኖ አያሳድሩም። የፕሮቶኮል መዛባት ከተሳታፊ፣ከተመራማሪ ወይም ከምርምር ባለሙያዎችን ልመነጭ ይችላል።።
42) **‘‘Protocol Violation’’** means accidental or unintentional change to, or non-compliance with the IRB approved protocol without prior sponsor and IRB approval. Violations generally increase risk or decrease benefit,	42.”ፕሮቶኮል ጥሰት” ማለት በአጋጣሚ ወይም ሳይፈለግ ያለ ስነምግባር ኮሚቴ ወይም ሰፖንሰር ፈቃድ የተደረገ ለዉጥ ወይም የስነምግባር ኮሚቴን የጸደቀውን ፕሮቶኮል ያለቅድመ ስፖንሰር ወይም የምርምር ስነግባር ኮሜቴ ፈቃድ አለመከተል ማለት ነው። ጥሰቶች

affects the participant's rights, safety, or welfare, or the integrity of the data.	በአጠቃላይ ስጋትን የሚጨምራሉ ወይም ጥቅምን ይቀንሳሉ፣ የተሣታፊውን መብቶና ደኅንነት ወይም የመረጃውን ትክክለኛነት ላይ ተጽኖ ያሳድራል።
43) "**Proclamation** "means the Food and Medicine Administration Proclamation No. 1112/2019;	43."**አዋጅ**" ማለት የምግብና የመድኃኒት አስተዳደር አዋጅ ቁጥር 1112/2019 ነዉ
44) "**Serious Adverse Event** "means any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect;	44."**የከፉ የጎኒዮሽ ጉዳት**" ማለት በማንኛውም ሁኔታ ለሞት የሚዳርግ፣ ለህይወት አስጊ የሆነ በሆስፒታል ተኝተዉ የሚታከሙ ወይም ቋሚ/ከፍተኛ የአካል ጉዳት የሚያስከትል ወይም የዎሊድ ችግር ነዉ
45) "**Source Documents** "means original documents, data, and records such as hospital records, clinical and office charts, laboratory notes, memoranda, participants' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, participant files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial;	45. "**መነሻ ሰነድ**" ማለት ኦሪጅናል ሰነዶች ፣ ማህደሮች፣ እንደ ሆስፒታል ያሉ የህክምናና ብሮሸሮች፤የህክምና ላቦራቶሪ ማስታዎሻዎች፣ የተሰታፊዎች የዉሎ ማስታዎሻዎች፣የግምገማ ቅጾች ፣ የመድኃኒት እደላ ማህደሮች፣ አኦቶሜትድ መሳሪያዎች የተቀዱ መረጃዎች፣ የላቦራቶሪ ዉጤቶች የተሳታፊዎች ፋይል፣ ከስራዉ ጋር ግኑኝነት ካላቸዉ ሌሎች የስራ ክፍሎች የተገኙ ማረጃዎች፣ የራጅ መረጃዎች፣ ማረጋገጫ የተደረገባቸዉ ቅጂዎች።
46) "**Study coordinator** "means a qualified	46. "**የጥናት አስተባባሪ**" ማለት ተፈላጊ

professional who works with and under the direction of the Principal Investigator and supports, facilitates, and coordinates the daily clinical trial activities;	የትምህርት ዝግጅት ያለዉ ሆኖ ከዋናዉ ተመራማሪ አመራር ስርና አብሮ በመሆን የእለት ተእለት የህክምና ሙከራ ስራዎችን የሚገደግፍ፣ የሚያቻችና የሚያስተባብር ባለሙያ ነዉ።
47) "**Study participant''** means an individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control;	47. **"የጥናት ተሳታፊ"** ማለት የህክምና ሙከራዉ የሚደረግበትን ምርት ተቀባይ ወይም እንደ ማነጻጸሪያ የሚሳተፍ ግለሰብ ነዉ፡፡
48) "**Summary of product characteristics** " means a document describing the properties and the officially approved conditions of use of medicine and forms the basis of information for healthcare professionals on how to use the medicine safely and effectively;	48. **"የምርት ባህሪያት ማጠቃለያ"** ማለት የመድኃኒትን አጠቃላይ ባህሪይ፣ የተፈቀደበትን በሽታ ሁኔታ የሚገልጽና ለጤና ባለሙያዎች መድኃኒቱ የጎንዮሽ ጉዳት በማያደርስና ዉጤታማ በሚሆንበት መንገድ ለመጠቀም መሰረታዊ መረጃ የያዘ ሰነድ ነዉ፡፡
49) "**Trial master file** "means a repository of documents that collectively can be used by monitors, auditors, assessors, and sponsors to demonstrate that a clinical trial has been conducted in compliance with Good Clinical Practice and the approved protocol;	49. **"የህክምና ሙከራ ማስተር ፋይል"** ማለት የህክምና ሙከራዉ የተፈቀደዉን የሙከራ ፕሮቶኮልና የመልካም የህክምና ሙከራ ስርዓት መርሆችን ተከትሎ እየተሰራ መሆኑን ለማሳያት ተቆጣጠሪዎች፣ ኦዲተሮች፣ ገምጋሚዎችና ስፖንሰሮች የሚጠቀሙት የተከማቹ የህክምና ሙከራ ሰነዶች ማለት ነዉ።
50) "**Vulnerable population**" means individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not,	50. **"ተጋላጭ የህብረተሰብ ክፍል"** ማለት በህክምና ሙከራ ሳተፎ ፈቃደኝነት ተገቢ ቢሆንም ባይሆንም ሊገኙ የሚችሉ ጥቅሞችን በመጠበቅና ፈቃደኛ ባይሆኑ ድግሞ ሊደርስባቸዉ የሚችለዉን አሉታዊ

of benefits associated with participation or of a retaliatory response in case of refusal to participate. Examples are pregnant women and fetuses, minors, pediatrics, geriatrics, prisoners, persons with diminished mental capacity, and those who are educationally or economically disadvantaged.	ጉዳት ምላሽ በመስጠት በተጽዕኖ ሚስጥ ሊገቡ የሚችለ የህብረተሰብ ክፍሎች ማለት ነዉ፡፡
51) "**Protocol** "means a document that describes the objective, design, methodology, statistical considerations, and organization of the trial, giving background and rationale of the trial;	51. "**ፕሮቶኮል**" የሙከራውን ዓላማ፣ ንድፍ፣ ዘዴ፣ ስታቲስቲካዊ ሁኔታ እና አደረጃጀት የሚገልጽ ሰነድ ማለት ሲሆን የሙከራዉን መነሻና ምክንያት ይሰጣል።
52) "**Sponsor** "means an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial;	52. **"ስፖንሰር** " ማለት የህክመና ሙከራ ለመጀመር፣ ለመምራትና የበጀት ድጋፍ ኃላፊነት የሚወስድ ግለሰብ፣ ተቋም ወይም ድርጅት ነው።
53) Any expression in the masculine gender shall also apply to the feminine.	53. በዚህ መመሪያ ለወንድ ያታ የተገለጸዉ ሁሉ ለሴትጸታምተግባራዊይሆናል፡፡
3. Scope	**3.የተፈጻሚነት ወሰን**
3. This directive shall apply to the application, review, authorization, and inspection of good	3. ይህ መመሪያ ክህክምና ሙከራ በቀረቡ ምርቶች፣ መድኃኒቶች ወይም አዲስ መድኃኒት ዉህዶች፣

clinical practice of clinical trials conducted on investigational Products or new combinations of medicines, biological products including vaccines, new therapeutic regimens, diagnostic procedures, bioequivalence or bioavailability studies and medical procedures.	ክትባቶች ወይም ሌሎች ባዮሎጂካዊ ምርቶች፤ በአዲስ ሁኔታ ለህክምና የቀረቡ ምርቶች፤ አዲስ የምርመራ ሂደቶች ፣ የላቦራቶሪ ግብአቶች፤ የባዮኢኩቫሌንስ ወይም የባዮአቨላቪሊቲ ጥናቶችና ሌሎች እንደ ቀዶ ጥገና በሉ የህክምና ሂደት ላይ የህክምና ሙከራ ለማድረግ የሚቀርቡ ማመልከቻዎችን ለመገምገም ፤ ፈቃድ ለመስጠትና ፈቃድ በተሰጣቸዉ የህክምና ሙከራዎች ላይ መልካም የህክምና ሙከራ ቁጥጥር(እንስፔክሽን) ለማድረግ ተፈጻሚ ይሆናል፡፡

Chapter Two **Clinical Trial Application**	**ምዕራፍ ሁለት** **የህክምና ሙከራ ማመልከቻ**
4. General	4. አጠቃላይ
1. Any person interested in conducting a clinical trial shall apply to the authority in accordance with this directive and subsequent guidelines and procedures established by the authority.	1) **ማንኛውም የህክምና ሙከራ ለመስራት ፍላጎት ያለው ሰው የህክምና ሙከራ ማመልከቻውን፣ ባለስልጣን መስሪያ ቤቱ በሚያዘጋጃቸው በዚህ መመሪያ፣ እና ይህን መመሪያ ተከትለዉ በሚወጡ ጋይድላይንና አሰራሮች መሰረት ለባለስልጣኑ ማመልከት አለበት።።**
2. A clinical trial application shall be made by a sponsor or any person duly delegated by a sponsor.	2) **የህክምና ሙከራ ማመልከቻ በስፖንሰሩ ወይም ስፖንሰሩ በሚወከለው ሰው መደረግ አለበት።።**
3. All clinical trial applications shall be treated through the same criteria regardless of the applicant's identity, such as domestic, foreign, public sector, or private sector.	3) **ሁሉም የህክምና ሙከራ ማመልከቻዎች በተመሳሳይ መስፈርት ከአመልካቹ ማንነት ውጪ ለምሳሌ የሀገር ውስጥ፣ የውጭ፣ የመንግስት ሴክተር ወይም የግል ሴክተር ተብሎ ሳይለይ መዳኘት አለባቸው።።**
4. An application of clinical trial shall contain the documents and content following Annexes 1 and 2 attached to this directive.	4) **የህክምና ሙከራ ማመልከቻ ከዚህ መመሪያ ጋር አባሪ በተደረጉት ቅፅ 1 እና 2 ይዘቶች መሰረት መቅረብ አለበት።**
5. The sponsor shall be responsible for ensuring that, all the necessary documents are included in the application	5) **ስፖንሰሩ ሁሉም አሰፈላጊ ሰነዶች ከህክምና ሙከራ ማመልከቻው ጋራ መከተታቸውን የማረጋገጥ ኃላፊነት አለበት።።**
6. All the protocol and essential documents shall be presented in English.	6) **ሁሉም የህክምና ሙከራ ፕሮቶኮሎች እና አስፈላጊ ዶክመንቶች በእንግሊዘኛ ቋንቋ መቅረብ አለበቸው።።**
7. The clinical trial applicant shall submit one hard copy and soft shall have the authority's stamp and be returned to the applicant.	7) **የህክምና ሙከራ የሚያመለክት ሰው ፕሮቶኮሉን እና አስፈላጊ ዶክመንቶችን አንድ ሀርዲ ኮፒ እና ሶፍት ኮፒ በመጀመሪያ ማመልከቻ ላይ መቅረብ አለበት።። የሚሰጡ ኮመንቶችን ካካተቱ በኃላ፣**

	የመጨረሻውን የፕሮቶኮል እና አስላጊ ዶክመንቶችን ቅጂ በሁለት ሃርድ ኮፒ ቅጂ ማስገባት አለበት፤ ሲፈቀድም፣ አንደኛው የመጨረሻ ቅጂ የባለስልጣኑን ማህተም በመያዝ ለአመልካቹ መመለስ አለበት፡፡
8. All the additional participating trial sites shall be listed on the application in written form. Written agreement letters or support letters from all the trial site institutions shall be submitted.	8) ሁሉም ተጨማሪ ተሳታፊ የሙከራ ጣቢያዎች በማመልከቻው ላይ በጽሁፍ መዘርዘር አለባቸው። ከሁሉም ተቋማት የተፃፉ የስምምነት ደብዳቤዎች ወይም የድጋፍ ደብዳቤዎች መቅረብ አለበት።
9. For multi-center clinical trials, there shall be one country Principal Investigator to communicate with the authority and trained and qualified site principal investigator. In addition the trial centers may have site coordinator for all sites.	9) በብዙ ማእከል ለሚከናወኑ የህክምና ሙከራዎች ከባለስልጣኑ ጋር መረጃ ለመለዋወጥ አንድ ሀገራዊ ዋና ተመራማሪ መኖር አለበት እና በሌሎች ጣብያዎች ላይ የሰለጠነ እና ብቁ የሆነ የጣቢያ ዋና ተመራማሪ መኖር አለበት፡፡ በተጨማሪም የህክምና ሙከራ ጣብያዎች የጣብያ አስተባባሪ ሊኖራቸው ይችላል።
4. Protocol	**4. ፕሮቶኮል**
1) The protocol's contents shall be prepared as per Annex 4 of this directive. However, site-specific information may be provided on separate protocol page(s) or addressed in a separate agreement.	1) የፕሮቶኮሉ ይዘት ከዚህ መመሪያ ጋር የተያያዘውን ቁፅ 4ን መሰረት በማድረግ መዘጋጀት አለበት። ነገር ግን ጣቢያ-ተኮር መረጃ በተለየ የፕሮቶኮል ገጽ(ጾች) ላይ ሊሰጥ ወይም በተለየ ስምምነት ሊቀርብ ይችላል።
2) The protocol shall contain sufficient safety and efficacy data from non-clinical studies and clinical trials to identify human exposure by route, dosages, and duration in the trial population to be studied as applicable.	2) ፕሮቶኮሉ እንደ አስፈላጊነቱ በቂ የሆነ የደኅንነትና የፈዋሽነት መረጃ ከህክምና ሙከራ ካልሆኑ እና የህክምና ሙከራዎች የሰዎችን ተጋላጭነት በአወሳሰድ መንገድ፣ በመጠንና በቆይታ በመለየት መያዝ

	አለበት፡፡
3) The protocol shall clearly state the availability of necessary resources for the completion of the trial and the disclosure of conflicts of interest by the investigators.	3) ፕሮቶኮሉ ለህክምና ሙከራው ማጠናቀቂያ አስፈላጊ የሆኑ ግብዓቶች መኖራቸውን እና የተመራማሪዎችን የጥቅም ግጭቶች ይፋ ማድረግ አለበት።
4) The authority may request additional information and documents depending on the nature of the clinical trial.	4) ባለሥልጣኑ እንደ ህክምና ሙከራው ሁኔታ ተጨማሪ መረጃ እና ሰነዶችን ሊጠይቅ ይችላል።
5) The protocol shall indicate the procedures for detection and management and timeline for reporting of AEs.	5) ፕሮቶኮሉ የጎንዮሽ ክስተቶችን መለየትን፣ ሪፖርት ማድረግን እና ማስተዳደርን እና ሪፖርት ማድረጊያ የሂዜ ሰሌዳዎችን ማመልከት አለበት።
6) The protocol shall contain clear criteria for stopping and terminating the clinical trial.	6) ፕሮቶኮሉ የህክምና ሙከራውን ለማቆም እና ለማቋረጥ ግልጽ የሆኑ መስፈርቶችን መያዝ አለበት።
7) Qualification of the clinical trial study team	**7) የህክምና ሙከራ ጥናት ቡድን ብቃት**
1) All the clinical trial team, including the investigator (s), shall have the required educational qualification, experience relevant to the clinical trial and good clinical Practice training, and provide evidence thereof.	1. ሁሉም የህክምና ሙከራ ቡድን አባላት ተመራማሪዎችን ጨምሮ የሚፈለገውን የትምህርት ብቃት፣ ስልጠና እና ልምድ ከሚካሄደው የህክምና ሙከራ ጋር ተዛማጅነት ያለው ማስረጃ ያላቸው መሆን አለበት፡፡ እንዲሁም ማስረጃዎቹ ለባለስልጣኑ ማቅረብ አለባቸው።
2) All clinical trial study team shall have formal training in good clinical practice within the last three years. Evidence of attending GCP courses shall also be submitted.	2. ሁሉም የህክምና ሙከራ ጥናት ቡድን በመልካም የህክምና ሙከራ ስርዓት መርሆዎች ላይ የሰለጠኑ መሆን አለባቸው፡፡ ስልጠናውን

	ስለመውሰዳቸውም የምስክር ወረቀቱ ከማመልከቻው ጋር መያያዝ አለበት።
3. Principal Investigators shall generally be physicians with a deep understanding of health and medicine and must be knowledgeable in their research fields. Depending on the circumstances, the authority may allow other health professionals to be the Principal Investigator of a clinical trial, provided that a study physician exists as a clinical trial team member.	3) እንደ አጠቃላይ ዋና ተመራማሪዎች ስለ ጤና እና መድኃኒት እንዲሁም ስለሚሰሩት የምርምር ፊልድ ጥልቅ እወቀት ያላቸው ሀኪሞች መሆን አለባቸው፡፡ እንደየሁኔታው ባለሥልጣኑ የጥናት ሀኪም የህክምና ሙከራ ቡድን አባል ከተካተተ ሌሎች የጤና ባለሙያዎች የህክምና ሙከራ ዋና ተመራማሪ እንዲሆኑ ሊፈቅድ ይችላል።
4. Not with standing sub article 3 of this article, depending on the nature of the clinical trial the authority may require a qualified clinical trial team member with specific specialty on the area	4) በዚህ አንቀፅ ንዑስ አንቀፅ 3 ላይ የተጠቀሰው እንዳለ ሆኖ፣ እንደ ህክምና ሙከራው ሁኔታ ባለስልጣኑ የተለየ ስፔሻሊቲ ያለው የጥናት ቡድን አባል ሊጠይቅ ይችላል፡፡
5. The updated curriculum vitae (CV) and official work experience letter of all the clinical trial study team shall be submitted during application.	5) የህክምና ሙከራ መማመልከቻ ሲገባ የሁሉም የጥናት ቡድኑ አባላት ወቅታዊ የስራ ልምድ ማሰረጃ እና የስራ ልምድን የሚገልፅ ደብዳቤ አብሮ መቅረብ አለበት፡፡
8. Investigational product	8) **የምርምር ምርት**
1. Investigational products shall be manufactured, handled, and stored following the current Good Manufacturing Practice (GMP) guideline for investigational products and used following the approved protocol.	1. የምርምር ምርቶች የሚመረቱት፣ የሚያዙት እና የሚከማቹት የዓለም ጤና ድርጅት ለናናምና ሙከራ ምርቶች ያወጣውን የመልካም አመራረት ስርዓት መመሪያ ተከትለው መሆን አለባቸው። እንዲሁም ጥቅም ላይ የሚውሉት በባለስልጣኑ የፀደቀውን ፕሮቶኮል በመከተል መሆን

	አለበት፡፡
2. The sponsor shall submit a valid Good Manufacturing Practice certificate issued by the competent national authority of the country of origin of the investigational product. The content of the investigational product GMP certificate shall follow Annex 7, attached to this directive.	2. ስፖንሰሩ የምርምር ምረቱ በተመረተበት ሀገር ባለስልጣን የተሰጠ የመልካም አመራረት ሰርተፍኬት ማቅረብ አለበት፡፡ የመልካም አመራረት ሰርተፍኬቱ ይዘትም በዚህ መመሪያ ላይ አባሪ የተደረገውን ቅፅ 7ን መከተል አለበት፡፡
3. The sponsor shall submit signed and dated certificate of Analysis for the investigational product.	3. ስፖንሰሩ የተፈረመና ቀንኑ የተገለፀበት የምርምር ምረቱን የጥራት ምርመራ ማረጋገጫ ሰርተፍኬት መቅረብ አለበት፡፡
4. The investigational product shall not be imported unless the clinical trial is authorized and the authority issues an import permit.	4. የህክምና ሙከራው እስኪፈቀድ እና ምርቱን ወደ ሀገር ውስጥ ለማስገባት በባለስልጣኑ ፈቃድ ካልተሰጠው በስተቀር የምርምር ምርት ወደ ሀገር ውስጥ ማስገባት አይፈቀድም፡፡
5. Authorization shall be required for the total or partial manufacture of an Investigational Product, including the various processes of dividing up, packaging, or presentation	5. የምርምር ምርትን ሙሉ በሙሉም ሆነ በከፊል የተለያዩ የመከፋፈል፣ የማሸግ ወይም የአቀራረብ ሂደቶችን ጨምሮ ሀገር ውስጥ ለማምረት የባለስልጣኑ ፈቃድ ያስፈልጋል።
6. A registered and licensed pharmacist shall handle and manage the investigational product.	6) የምርምር ምርቱ በተመዘገበ እና ፈቃድ ባለው የፋርማሲ ባለሙያ መያዝና መተዳደር አለበት፡፡
7. Notwithstanding sub article 5 of this article, other healthcare professional may handle and manage the investigational products as necessary.	7) በንዑስ አንቀፅ 6 ላይ የተጠቀሰው እንዳለ ሆኖ፣ ሌሎች የጤና ባሙያዎች እንዳስፈላጊነቱ የምርምር ምርት ሊይዙ እና ሊያስተዳድሩ ይችላሉ፡፡
8. Authorization for the importation and use of the investigational product shall apply only to the	8) የምርምሩን ምርት የማስመጣት እና የመጠቀም ፍቃድ በማመልከቻው ውስጥ

premises specified in the application and to the types of medicinal products and pharmaceutical forms specified in that application.	በተገለጹት ቦታዎች ላይ ብቻ የተወሰነ እና የመድኃኒት ቅርጾችም በዚያ ማመልከቻ ውስጥ በተገለጹት መሰርት ብቻ ተፈጻሚ ይሆናል።
9. Access to the investigational product shall be limited strictly to the authorized professionals according to the procedure indicated in the clinical trial protocol.	9) በፕሮቶኮሉ ላይ በሚጠቀሰው የአሰራር ሂደት መሰረት የምርመር ምርት ከተፈቀደላቸው ባለሙያዎች ውጪ መያዝ የተከለከለ ነው፡፡
10) The investigational product shall be labeled "for clinical trial use only."	10. የምርምሩ ምርት የመግለጫ ፅሁፍ "ለህክምና ሙከራ አገልግሎት ብቻ" ተብሎ መለየት አለበት።
11. The record of the quantities of IP received, used, and left for the trial under conduct must be documented and shall be part of the progress report.	11) የምርምር ምርቱ መጠን የተወሰደው፣ አገልግሎት ላይ የዋለው እና የቀረው መመዝገብ እና የሂደት ሪፖርቱ አካል መሆን አለበት።
12. Unless the authority authorizes for compassionate use, the investigational product not used or left from the clinical trial shall be disposed of following medicinal waste management and disposal directive, and a certificate of destruction or disposal shall be submitted with the completion of the study report.	12) ባለሥልጣኑ በርኅራኄ ጥቅም ላይ እንዲውል ካልተፈቀደ በስተቀር፣ ለህክምና ሙከራው ጥቅም ላይ ያልዋለው ወይም ከህክምናው ሙከራው የተረፈው የምርምር ምርት የመድኃኒት ማስወገጃ መመሪያን ተከትሎ መወገድ አለበት እና የዚህ ማረጋገጫ ሰርተፍኬት ጥናቱ ሲጠናቀቅ ከጥናቱ ሪፖርት ጋር አብሮ መቅረብ አለበት፡፡
13. The Authority may request full or brief description of chemistry, manufacturing and control of investigational product.	13) ባለሥልጣኑ ስለ ኬሚስትሪ፣ ስለማምረት እና ስለምርመራ ምርቶች ቁጥጥር ሙሉ ወይም አጭር መግለጫ ሊጠይቅ ይችላል።

14) Procedures for receiving, storing, securing, dispensing, documenting, reconciling, and returning/ destroying of Investigational products must be in place.	14. የምርመራ ምርቶችን የመቀበል፣ የማከማቸት፣ የማቆየት፣ የማከፋፈል፣ የመመዝገብ፣ የማስታረቅ እና የመመለስ/የማስወገድ አሰራሮች መኖር አለባቸው።
9. Investigator's Brochure	**9) የተመራማሪው ብሮሸር/ሰነድ**
1. An updated Investigator's brochure shall be submitted during application.	1) የህምና ሙከራ ማመልከቻ በሚቀርብበት ወቅት ወቅታዊ የሆን የተመራማሪ ብሮሸር መቅረብ አለበት፡፡
2. The investigator's brochure, including any update, shall include a summary of the proposed use of the investigational product, justification for the dose, dose steps, dose rationale, route of administration, schedule, treatment duration, and dose modifications.	የተመራማሪው ብሮሸር ማንኛውንም ማሻሻያ ጨምሮ የምርምሩን ምርት አጠቃቀም ማጠቃለያ፣ የመጠን ማረጋገጫ፣ የመጠን ደረጃዎች፣ የመጠን ምክንያታዊነት፣ የአወሳሰድ መንገድ፣ የጊዜ ሰሌዳ፣ የህክምና ቆይታ እና የመጠን ማሻሻያዎችን ማካተት አለበት።
3. The information under sub-article (2) shall be presented in a concise, simple, objective, balanced, and non-promotional form that enables a clinician or potential investigator to understand it and make an unbiased risk-benefit assessment of the appropriateness of the proposed clinical trial	2) በንኡስ አንቀጽ (1) ስር ያለው መረጃ ሀኪም ወይም ተመራማሪው ሊረዳው በሚችል አጭር፣ ቀላል፣ ተጨባጭ፣ ሚዛናዊ እና አስተዋዋቂ ባልሆነ እንዲሁም የታቀደው የህክምና ሙከራ ተገቢነት ላይ አድሎ የለሽ የጉዳትና-ጥቅም ግምገማ በሚያደርግ መልኩ መቅረብ አለበት።
4. When the investigational product has marketing authorization, the Summary of Product Characteristics may be used instead of the investigator's brochure.	3) የምርምሩ ምርቱ የገበያ ፍቃድ ያለው ሲሆን፣ ከተመራማሪው ብሮሸር ይልቅ የተጠቃለለ የምርት ባህሪያት መረጃ ጥቅም ላይ ሊውል ይችላል።
5. The sponsor shall regularly validate, update and submit the investigator's brochure to the authority whenever there is new information.	4) አዲስ መረጃ በተገኘ ቁጥር ስፖንሰሩ የተመራማሪውን ብሮሸር በየጊዜው ማጽደቅ፣ ማዘመን እና ለባለስልጣኑ ማቅረብ አለበት።

10. Informed Consent	**10. በመረጃ የተደገፈ ስምምነት**
1. A clinical trial shall be conducted only on participants who consented after all relevant information provided to them to make an informed decision.	1) **የህክምና ሙከራ የሚካሄደው በመረጃ ላይ የተመሰረተ ውሳኔ እንዲያደርጉ ከተሰጣቸው ሁሉም አስፈላጊ መረጃዎች በኋላ ፈቃደኛ በሆኑ ተሳታፊዎች ላይ ብቻ ነው።**
2. Informed consent shall be: A. Obtained from the participants before they participate in a clinical trial. B. Documented in written format. C. Freely given, prepared in the language that the participant can understand and read with sufficient time, and signed prior to clinical trial participation.	2) **በመረጃ የተደገፈ ስምምነት ፈቃድ፡-** **ሀ) በህክምና ሙከራ ውስጥ ከመሳተፋቸው በፊት ከተሳታፊዎች መወሰድ አለበት፣** **ለ) በፅሁፍ የተሰነደ መሆን አለበት** **ሐ) በነጻነት የተሰጠ፣ ተሳታፊው በሚረዳው ቋንቋ የተዘጋጀ እና በቂ ማንበቢያ ጊዜ የተሰጠው፣ በምስክር የተረጋገጠ እና የህክምና ሙከራው ከመጀመሩ በፊት የተፈረመ መሆን አለበት።**
3. Participants who cannot read and write shall sign the informed consent form after proper reading and explaining the contents of the informed consent form by a family or guardian, or witness.	3) **ማንበብ እና መጻፍ የማይችሉ ተሳታፊዎች በመረጃ የተሰጠውን የስምምነት ቅጽ መፈረም ያለባቸው በመረጃ የተሰጠው የስምምነት ቅጽ በቤተሰብ ወይም በአሳዳጊ ወይም በምስክር በትክክል ከተነበበላቸው በኋላ መሆን አለበት።**
4. In clinical trials involving minors, the minor shall participate only with the consent of the parent or guardian and assent obtained for the minor 12-17 years old.	4) **ለአካለ መጠን ያልደረሱ ሕፃናትን በሚያካትቱ የህክምና ሙከራዎች፣ አካለመጠን ያልደረሱ ልጆች በወላጅ ወይም በአሳዳጊ ፈቃድ እና ከ12 ዓመት በላይ ለሆነ ህጻናት ተጨማሪ ስምምነት ሲኖር ብቻ ነው መሳተፍ ያለባቸው።**
5. Not withstanding subarticle 4 of this article, minor	5) **የዚህ አንቀጽ ንኡስ አንቀጽ** 4

participant shall be re-conscented and give informed consent when they reach the age of 18 years while they are in the clinical trail.	እንደተጠበቀ ሆኖ ለአካለ መጠን ያልደረሰ ልጅ አስራ ስምንት አመት ሲሞላዉ ፈቃዱን እንደአዲስ መስጠት አለበት።
6. In emergency situations, when prior consent of the participant is not possible, the consent of the participant's legally acceptable representative, if present, should be requested.	6) በደንገተኛ ሁኔታዎች ወቅት ከህክምና ሙከራ ተሳታፊው ቅደመ ስምምነት መውሰድ በማይቻልበት ጊዜ ከተሳታፊው ህጋዊ ተቀባይናት ካለው ተወካይ ስምምነት መጠየቅ አለበት።
7. Notwithstanding to sub article (6) When the participant's legally acceptable representative is not available, enrolment of the participant should require measures described in the protocol and/or elsewhere, with documented approval/favorable opinion by the IRB/IEC, to protect the rights, safety and well-being of the participant.	7) በንዑስ አንቀፅ 6 ላይ ያለው እንዳለ ሆኖ የተሳታፊው ህጋዊ ተቀባይነት ያለው ተወካይ በማይኖርበት ወቅት፣ ተሳተፊውን ወደ ህክምና ሙከራ ለማስገበት በፕሮቶኮሉ ላይ ወይም ሌላ ሰነድ ላይ በሚቀመጠው አሰራር መሰረት እና በሚመለከተው የስነ ምግባር ኮሚቴዎች ይሁንታን አግኝቶ የተሳታፊን መብትና ደህንነት ያረጋገጠ መሆን አለበት።
8. The participant or the participant's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate should be requested.	8) ተሳታፊው ወይም የተሳታፊው ህጋዊ ተቀባይነት ያለው ተወካይ ስለ ህክምና ሙከራው ወድያውኑ መረጃ ሊደርሳቸውና ለመቀጠል ወይም እንዳስፈላጊነቱ ሌላ ስምምነት መጠየቅ አለበት።
9. It is prohibited to use the data or samples for the participants who withdrew consent during the study. The data/sample before they withdrew can be used.	9) ተሳታፎች የሰጡትን ስምምነት ካቋረጡ በኃላ በጥናቱ ውስጥ መረጃቸውን ወይም ናሙናቸውን መጠቀም ፈፅሞ የተከለከለ ነው።ስምምነቱን ሳያቋረጡ በፊት የነበረውን መረጃ ወይም ናሙና መጠቀም ይቻላል።
10. For clinical trials conducted on vulnerable population group, written consent shall be	10) ተጋላጭ የሆኑ የህብረተሰብ ክፍል ላይ ለሚሰሩ የህክምና ሙከራዎች ከተሳታፎቹ

obtained from other concerned body in addition to the participant as necessary.	በተጨማሪ በፅሁፍ የተደገፈ ስምምነት ከሚመለከታቸው አካላት (የአእምሮ ቸግር ላለባቸው ከሞግዚት/ተንከባካቢ፣ ለነብሰ ጡር እናት ከባለቤቷ፣ ወዘተ.) መውሰድ አስገላጊ ነው፡፡

CHAPTER THREE **CLINICAL TRIAL PROTOCOL REVIEW AND AUTHORIZATION**	**ምዕራፍ ሶስት** **የህክምና ሙከራ ፕሮቶኮል ግምገማ እና ፍቃድ**
10. Screening 1. The authority shall screen the clinical trial application contents as per annex 1, 2, and 3 to determine if it is a clinical trial or not and if it is eligible for full review within seven working days of receiving the application	10. ማጣራት 1) ባለሥልጣኑ የህክምና ሙከራ ማመልከቻ ይዘቶችን በአባሪ 1 ፣ 2 እና 3 መሠረት ያጣራል ፣ የህክምና ሙከራ መሆኑን ወይም አለመሆኑን እና ሙሉ ግምገማ ለማድረግ ብቁ መሆኑን ማመልከቻው በደረሰው በአስር የቀን መቁጠሪያ ቀናት ውስጥ ይወስናል፤
2) When the authority finds the application is a clinical trial and decides for a full review, it shall notify the applicant and provide the payment slip as per the current rate of service fee regulation of the Authority.	2) ባለሥልጣኑ ማመልከቻው የህክምና ሙከራ ሆኖ ሲያገኘው እና ሙሉ በሙሉ እንዲገመገም ሲወስን፣ አመልካቹን ማሳወቅ እና አሁን ባለው የባለሥልጣኑ የአገልግሎት ክፍያ ደንብ መሰረት የክፍያ ሰነዱን መስጠት አለበት፤
3) When the authority finds that the application is not a clinical trial or lacks the required document, it shall inform the applicant in writing, including the reason for a rejection or requirement for additional	3) ባለሥልጣኑ ማመልከቻው የህክምና ሙከራ እንዳልሆነ ወይም አስፈላጊው ሰነድ እንደሌለው ሲያረጋግጥ፣ ውድቅ

information.	የተደረገበትን ምክንያት ወይም አስፈላጊ የሆኑ ተጨማሪ መረጃዎችን ጠቅሶ ለአመልካቹ በጽሁፍ ያሳውቃል።
11. Review	**11.ግምገማ**
1) Clinical trial protocol and essential documents shall be reviewed by two or more experts.	1) ባለሥልጣኑ ፕሮቶኮሉን እና ሌሎች አስፈላጊ ሰነዶችን እንዲያዩ ሁለት ወይም ከዚያ በላይ ባለሙያዎችን ይመድባል፤
2) When necessary, the authority may use the external assessors and advisory committee to review the clinical trial application.	2) አስፈላጊ ሆኖ ሲገኝ የህክምና ሙከራ ማመልከቻን ለመገምገም ባለሥልጣኑ የውጪ ገምጋሚዎችን ወይም አማካሪ ኮሚቴን ሊጠቀም ይችላል፤
3) The authority may conduct a joint review of a clinical trial application with other countries' regulatory authorities and regional or international organizations based on agreements or collaborative initiatives. .	3) ባለሥልጣኑ በስምምነቶች ወይም በትብብር ተነሳሽነት ላይ በመመስረት ከሌሎች አገሮች ተቆጣጣሪ ባለሥልጣናት እና ከክልላዊ ወይም ዓለም አቀፍ ድርጅቶች ጋር የህክምና ሙከራ ማመልከቻን በጋራ ሊገመግም ይችላል፤
4) The Authority may recognize, receive and use the relevant CT decisions, reports or information from other NRAs, regional and international bodies like WHO, AVAREF, EMA and USFDA	4) ባለስልጣን መስሪያ ቤቱ ሌሎች ተቆጣጣሪ አካላት ወይም ዓለም አቀፍ ተቋማትን የሰጡትን ግምገማ ሪፖረት ይቀባላል እንደአስፈላጊነቱ ጥቅም ላይ እንዲዉሉ ያደርጋል
5) The time of review at the authority shall be 45 working days to handle a duly completed application (including service fee) for first	5) በትክክል ተጠናቆ ለባለስልጣኑ ለቀረበ ማመልከቻ በ45 የስራ ቀናት ውስጥ ተገምግሞ የመጀመሪያ ግብረመልስ መሰጠት

feedback; however, the review for a clinical trial with high risk may be extended up to 90 calendar days.	አለበት; ሆኖም የስጋት ደረጃው ከፍተኛ ለሆነ የህክምና ሙከራ የግምገማ ጊዜው እስከ 90 ቀናት ሊራዘም ይችላል፤
6) The applicant shall submit the response within six months of receiving the authority's feedback.	5) ከአቅም በላይ የሆነ ምክንያት ከሌለ በቀር አመልካቹ፤ የባለስልጣኑ አስተያየት በደረሰው በስድስት ወራት ውስጥ ምላሹን ማቅረብ አለበት። በስድስት ወራት ውስጥ ምላሽ መስጠት ካልተቻለ አመልካች ለባለሥልጣኑ ማሳወቅ አለበት፤
6) Not withstanding sub article 5 of this article, if it is not possible to respond in six months, the applicant shall notify the Authority before the elapse of the six month.	6. የዚህ አንቀፅ ንኡስ አንቀጽ 5 እንደተጠበቀ ሆኖ በስድስት ወራት ውስጥ ምላሽ መስጠት ካልተቻለ አመልካች ስድስት ወር ከማለፉ በፊት ለባለሥልጣኑ ማስታወቅ አለበት።
7) When there is no sufficient justification for the delay, the authority rejects responses made after six months and notifies the applicant to make a new application to proceed with the trial	7. ለመዘግየቱ በቂ ምክንያት ከሌለ ባለሥልጣኑ ከስድስት ወራት በኋላ የተሰጡትን ምላሾች ውድቅ ያደርግ እና፤ አመልካቹ፤ ጥናቱን ለመቀጠል አዲስ ማመልከቻ እንዲያቀርብ ያሳውቃል፤
8. The application shall be rejected when the applicant cannot provide the requested information and make adequate changes to the protocol after feedback is provided in the form of a further request for three consecutive times.	8) አመልካቹ፤ የተጠየቀውን መረጃ ማቅረብ በማይችልበት ጊዜ እና በፕሮቶኮሉ ላይ በቂ ለውጦች እንዲደረጉ ለሦስት ተከታታይ ጊዜያት ተጨማሪ ጥያቄ ከቀረበለት በኋላ ሊያስተካክለው ካልቻለ ማመልከቻው ውድቅ ይደረጋል፤

9. The time of review for further replies shall be within 20 working days.	9) ለተጨማሪ ምላሾች የግምገማው ጊዜ በ 30 የቀን መቁጠሪያ ቀናት ውስጥ መሆን አለበት፤
10. The Authority shall review post-authorization safety reports, including non-compliance. As necessary, the Authority may use the National Clinical trial advisory committee.	10)ባለሥልጣኑ ከፈቃድ በኋላ ያሉ የደህንነት ሪፖርቶችን እና ጥሰቶችን ጨምሮ ይገመግማል እንደ አስፈላጊነቱ ባለሥልጣኑ የብሔራዊ የህክምና ሙከራ አማካሪ ኮሚቴን ሊጠቀም ይችላል።
12. **Non-Routine Procedures for Clinical Trial Review**	12.**ለህክምና ሙከራ ግምገማ መደበኛ ያልሆኑ ሂደቶች**
1) The authority may undertake an expedited review of a clinical trial application.	1) ባለሥልጣኑ ለህክምና ሙከራ ማመልከቻ ፈጣን ግምገማ ሊያደርግ ይችላል፤
2) A clinical trial shall qualify for expedited review where one of the following criteria is present after consideration of risks and benefits associated with the clinical trial. A. The investigational product is intended to treat a serious or life-threatening condition; B. Available data on the investigational product demonstrates the potential to address an unmet medical need, especially during a national epidemic, a global pandemic, or other similar emergencies;	2) የህክምና ሙከራ ከህክምና ሙከራው ጋር ተያይዘው የሚመጡ አደጋዎችን እና ጥቅሞችን ከግምት ውስጥ ካስገባ በኋላ ከሚከተሉት መመዘኛዎች ውስጥ አንዱ ሲገኝ ለተፋጠነ ግምገማ ብቁ ይሆናል። ሀ) የምርምር ምርቱ ለከባድ ወይም ለሕይወት አስጊ የሆነ ሁኔታን ለማከም የታሰበ ሲሆን፤ ለ) በምርምር ምርቱ ላይ ያለው መረጃ ያልተሟላ የህክምና ፍላጎትን በተለይም በአገር አቀፍ ወረርሽኝ ወቅት፣ አለምአቀፍ ወረርሽኝ ወይም ሌሎች ተመሳሳይ ድንገተኛ አደጋዎችን የመፍታት አቅም እንዳለው ሲያሳይ፤

3) The authority may initiate the expedited review with its initiation or based on the applicant's request.	3) ባለሥልጣኑ የተፋጠነ ግምገማውን በራሱ ተነሳሽነት ወይም በአመልካቹ ጥያቄ መሰረት ሊጀምር ይችላል፤
4) Expedited review shall not take more than 30 calendar days after receipt of a complete clinical trial application.	4) የተሟላ የህክምና ሙከራ ማመልከቻ ከተቀበለ በኋላ፤ የተፋጠነ ግምገማ ከ 30 የቀን መቁጠሪያ ቀናት በላይ መውሰድ የለበትም።
5) The applicant shall submit an application following Annex 9 when applying or requesting clinical trials for non-routine clinical trial procedures in addition to the documents required to be submitted.	5) አመልካች መደበኛ ላልሆኑ የህክምና ሙከራዎች በሚያመለክትበት ወይም በሚጠይቅበት ጊዜ፤ ለመደበኛ የህክምና ሙከራዎች ከሚቀርበው ሰነድ በተጨማሪ አባሪ 9ን በመከተል ማቅረብ አለበት፣
6) The applicant shall submit the response within 30 days of receiving the authority's feedback. When there is no sufficient justification for the delay, the authority rejects responses made after 30 days and notify the applicant to make a new application to proceed with the trial.	6) አመልካቹ፣ የባለሥልጣኑን አስተያየት ከተቀበለ በኋላ በ 30 ቀናት ውስጥ ምላሹን ማቅረብ አለበት። ለመዘግየቱ በቂ ምክንያት ከሌለ ባለሥልጣኑ ከ 30 ቀናት በኋላ የተሰጡትን ምላሾች ውድቅ በማድረግ ለአመልካቹ የህክምና ሙከራውን ለመቀጠል አዲስ ማመልከቻ እንዲያቀርብ ያሳውቃል።
7) The time of review for further replies shall be within 15 calendar days.	7) ለተጨማሪ ምላሾች የግምገማ ጊዜ በ 15 የቀን መቁጠሪያ ቀናት ውስጥ መሆን አለበት ።
8) The application shall be rejected when the applicant cannot provide the requested information and make adequate changes to the protocol after feedback is provided in the form of a further	8) ለሦስት ተከታታይ ጊዜያት ተጨማሪ ጥያቄ ከተጠየቀ በኋላ፤ አመልካቹ የተጠየቀውን መረጃ ማቅረብ በማይችልበት ጊዜ እና በፕሮቶኮሉ ላይ

request for three consecutive times.	በቂ ለውጦችን ለማድረግ ካልቻለ፤ ማመልከቻው ውድቅ ይደረጋል።
9) The authority may authorize to be conducted clinical trials on vulnerable populations in special conditions based on scientifically justifiable evidence and depending on risk-benefit analysis	9) ባለሥልጣኑ በሳይንስ ሊረጋገጡ በሚችሉ ማስረጃዎች እና በጥቅም እና ጉዳት ትንተና ላይ በመመርኮዝ ለአደጋ ተጋላጭ በሆኑ ሰዎች ላይ በልዩ ሁኔታ የህክምና ሙከራዎች እንዲደረጉ ሊፈቅድ ይችላል
13. Insurance and Compensation 1) Any clinical trial shall have adequate insurance coverage for all human participants participating in the trial and submit the evidence to the authority.	**13.መድን እና ማካካሻ** 1) ማንኛውም የህክምና ሙከራ በሙከራው ውስጥ ለሚሳተፉ ለሁሉም የሰው ልጆች በቂ የመድን ሽፋን ሊኖረው እና ማስረጃውን ለባለስልጣኑ ማቅረብ አለበት፤
2) The sponsor shall pay adequate compensation to participants of the clinical trial for injuries inflicted directly or indirectly due to their participation in the clinical trial.	2) የህክምና ሙከራ ተሳፊዎች በህክምና ሙከራው ውስጥ በመሳተፋቸው በቀጥታም ሆነ በተዘዋዋሪ ለደረሰባቸው ጉዳቶች ስፖንሰር አድራጊው በቂ ማካካሻ መክፈል አለበት፤
3) Compensation shall be paid to the lawful beneficiaries or heirs where the participant dies due to the injury caused directly or indirectly due to participation in the clinical trial.	3) በህክምና ሙከራው ውስጥ በመሳተፍ በቀጥታም ሆነ በተዘዋዋሪ በደረሰው ጉዳት ተሳታፊው ከሞተ ህጋዊ ለሆኑ ተጠቃሚዎች ወይም ወራሾች ካሳ ይከፈላል፤
4) The sponsor or investigator shall have the duty to provide adequate medical care with a qualified physician to a participant for any adverse events faced during or following his	4) የጥናት ተሳታፊው በህክምና ሙከራ ውስጥ በተሳተፈበት ጊዜ ወይም ከዚያ በኋላ ላጋጠሙት ማናቸውም አሉታዊ ሁኔታዎች ስፖንሰር አድራጊው ወይም ዋና ተመራማሪው

participation in the trial.	ብቃት ካለው ሐኪም ጋር በመሆን በቂ የሕክምና እንክብካቤ የመስጠት ግዴታ አለበት፤
5) Standard medical care related to participation in the clinical trial shall be given to the participants without any fee, and emergency and rescue medications shall be available on the site.	5) በህክምና ሙከራ ውስጥ ከመሳተፍ ጋር የተያያዘ መደበኛ የሕክምና አገልግሎት ለተሳታፊዎች ያለ ምንም ክፍያ መሰጠት አለበት, እንዲሁም የድንገተኛ እና የማዳን መድሃኒቶች ጥናቱ በሚካሄድበት ስፍራ መኖር አለበት፤
6) Clinical trial participants should be reasonably reimbursed for costs directly incurred during the trial, such as travel costs, and compensated reasonably for their inconvenience and time spent. Compensation can be monetary or non-monetary.	6) የህክምና ሙከራ ተሳታፊዎች በሙከራው ወቅት በቀጥታ ለሚያወጡት ወጪ፣ እንደ የጉዞ ወጪ እና ለችግር እና ለጠፋው ጊዜ ተመጣጣኝ ማካካሻ ሊደረግላቸው ይገባል። ማካካሻው የገንዘብ ወይም የገንዘብ ያልሆነ ሊሆን ይችላል፤
7) Compensation must not be exaggerated to induce potential participants to consent to participate in the trial against their better judgment (“undue inducement”). The independent ethics committee must approve reimbursement and compensation for research participants.	7) ነፃ የሆነ የመሳተፍ ውሳኔያቸውን በሚፃረን መልኩ (ተገቢ ያልሆነ ተነሳሽነት) የማካካሻ ክፍያ የተጋነነ መሆን የለበትም። ገለልተኛ የሆነ የስነ-ምግባር ኮሚቴ ለምርምር ተሳታፊዎች የሚከፈለውን ማካካሻ ማጽደቅ አለበት.
14. Authorization of a clinical trial	**14.የህክምና ሙከራ ፍቃድ**
1) After the protocol is reviewed in detail and found acceptable, the authority shall give a written letter stating authorization for the clinical trial to be conducted in the country.	1. ፕሮቶኮሉ በዝርዝር ከተገመገመ እና ተቀባይነት ያለው ሆኖ ከተገኘ፣ ባለሥልጣኑ ህክምና ሙከራው በአገሪቱ ውስጥ እንዲካሄድ ፈቃድ ማግኘቱን የሚገልጽ የጽሁፍ ደብዳቤ ይሰጣል፤

2) A clinical trial shall be Authorized for the duration of the trial.	2. **የህክምና ሙከራ ፈቃድ የሚሰጠው የህክምና ሙከራዉ ሊጠናቀቅ እስከታቀደዉ ጊዜ ድረስ ነዉ።**
3) Annualy renewed Ethics approval shall be submitted to the authrotity.	3. **የታደሰ የስነምግባር ማረጋገጫ ፈቃድ በየአመቱ ለባለስልጣኑ መቅረብ አለበት።**
4) If the clinical trail is not completed during the Authorized period of time, extension request shall be submitted in the form of amendment.	4. **በታቀደዉ ጊዜ ውስጥ የህክምና ሙከራዉ ካልተጠናቀቀ የህክምና ሙከራ ፈቃድ በማራዘም እንዲታደስ በማሻሻያ ቅዝ ለባለስልጣኑ መቅረብ አለበት።**
5) Re-initiation of the clinical trial may be considered if satisfactory justifications and acceptable corrective measures are taken.	5. **አጥጋቢ ማስረጃዎች እና ተቀባይነት ያላቸው የማስተካከያ እርምጃዎች ከተወሰዱ የህክምና ሙከራውን እንደገና ለመጀመር ሊታሰብ ይችላል።**
6) The authority shall take the appropriate measures against any clinical trial conducted without authorization or renewal.	6. **ባለሥልጣኑ ያለፈቃድ ወይም ያለፈቃድ ማራዘሚያ እድሳት በሚደረግ ማንኛውም የህክምና ሙከራ ላይ ተገቢውን እርምጃ ይወስዳል፤**
7) Placebo-controlled clinical trial in which one group gets the active treatment and the other gets the placebo is prohibited with a disease or condition for which treatment with proven efficacy is available.	7. **ውጤታማነቱ የተረጋገጠ ህክምና ባላቸው በሽታዎች ላይ ፈዋሽ ንጥረነገር የሌላቸው መድሃኒቶችን በመጠቀም ማትም አንደኛው ቡድን ፈዋሽ ንጥረነገር ያለውን ሌላኛው ደግሞ የሌለውን እንዲወስዱ አድርጎ መስራት የተከለከለ ነው**

8) All approved and rejected clinical trial applications and summary evaluation reports shall be listed and made publicly available and periodically updated in an easily accessible local or international database.	8. ሁሉም ተቀባይነት ያገኙ እና ውድቅ የተደረገ የህክምና ሙከራ ማመልከቻዎች እና የግምገማ ሪፖርቶች ማጠቃለያ ተዘርዝረው ለህዝብ እንዲቀርቡ እና በየጊዜው በቀላሉ ተደራሽ በሆነ የሀገር ውስጥ ወይም አለምአቀፍ የመረጃ ቋት ውስጥ መዘመን አለባቸው።
CHAPTER FOUR **CONDUCT AND AMENDMENT OF THE CLINICAL TRIAL**	**ምዕራፍ አራት** **የህክምና ሙከራ ትግበራ እና ማሻሻያ**
15. <u>Conduct of the Clinical Trial</u>	**15.<u>የህክምና ሙከራን ማካሄድ</u>**
1) It shall be prohibited to conduct any clinical trial on humans before obtaining authorization from the authority.	1. ማመልከቻ ከመቅረቡ በፊት እና ከባለስልጣኑ ፈቃድ ከማግኘቱ በፊት በሰዎች ላይ ማንኛውንም የህክምና ሙከራ ማድረግ የተከለከለ ነው፤
2) A clinical trial shall be conducted only in a site that has the capacity to condut clinical trial and has been given a certificate of competence for health care delivery or clinical research from an appropriate governmental organization.	2. የህክምና ሙከራ የሚካሄደው አግባብ ካለው የመንግስት ድርጅት ለጤና አገልግሎት አሰጣጥ ወይም ለህክምና ምርምር የብቃት ማረጋገጫ የምስክር ወረቀት በተሰጠው ተቋም ላይ ብቻ ነው፤
3) Clinical trials shall be conducted in compliance with the approved protocol, good clinical practice principles, national proclamation, regulation, directive and guidelines.	3. የህክምና ሙከራዎች በተፈቀደው ፕሮቶኮል መሰረት፤ መልካም የህክምና ሙከራ መርሆዎችን ተከትሎ፤ ብሔራዊ አዋጅ፣ ደንብና መመሪያን በማክበር ሊከናወኑ ይገባል፤
4) When there is protocol deviation or violation the investigator shall notify immediately to the authority.	4. ፕሮቶኮልን ማዛባት ወይም መጣስ ሲኖር ተመራማሪው ወዲያውኑ ለባለሥልጣኑ ማሳወቅ አለበት፤

5) Changes to eliminate immediate harm to trial participants or to take urgent safety measures may be implemented, and the change shall be notified immediately to the authority.	5. ለሙከራ ተሳታፊዎች ፈጣን ጉዳትን ለማስወገድ ወይም አስቸኳይ የደህንነት እርምጃዎችን ለመውሰድ ለውጦች ሊተገበሩ ይችላለ፤ ለውጡ ወዲያውኑ ለባለስልጣኑ ማሳወቅ አለበት፤
6) In blinded trials, the coding system for the investigational product(s) shall include a mechanism that permits rapid identification of the product(s) in case of a medical emergency but does not permit undetectable breaks of the blinding.	6. በተጋረዱ ሙከራዎች፣ የምርምር ምርት(ዎች) ኮድ አሰጣጥ ስርዓት በድንገተኛ አደጋ ጊዜ ምርቱን(ዎችን) በፍጥነት መለየት የሚያስችል ዘዴን ማካተት አለበት ነገር ግን ምክንያቱ ያልታወቀ መሸሸግን መፍቀድ የለበትም፤
7) After authorization, the clinical trial shall be initiated within three months; where enrolling the first participant is not possible, the investigator shall notify the authority with justification.	7. የህክምና ሙከራው ፈቃድ ባገኘ በሶስት ወራት ጊዜ ውስጥ መጀመር አለበት፤ የመጀመሪያውን ተሳታፊ መመልመል ካልተቻለ ተመራማሪው ችግሩን ከነማብራሪያው ለባለሥልጣኑ ማሳወቅ አለበት፤
8) The investigator shall notify the regulatory authority when enrolling the first participant	8. የመጀመሪያውን የጥናት ተሳታፊ ሲመዘግቡ ተመራማሪው ለቁጥጥር ባለስልጣኑ ማሳወቅ አለበት
9) All equipment used at the clinical trial shall be calibrated and conform to good laboratory practice.	9. በህክምና ሙከራ ውስጥ ጥቅም ላይ የሚውሉ ሁሉም መሳሪያዎች ተስተካክለው መልካም የላቦራቶሪ ተግባር ማስቻል አለባቸው፤
10) The authority may permit biological sample analysis outside the country. For those samples, the sponsor shall submit an approved material transfer agreement.	10. ባለሥልጣኑ ከአገር ውጭ የባዮሎጂካል ናሙና ትንተና ሊፈቅድ ይችላል፤ ለነዚያ ናሙናዎች፣ ስፖንሰር አድራጊው የተፈቀደ የቁሳቁስ ማስተላለፍ ስምምነት ማቅረብ አለበት።
11) Progress reports shall be provided to the authority biannually for trials having a study period of more than one year. For those trials with a study period of less than one year, the final report shall be	11. ከአንድ አመት በላይ የጥናት ጊዜ ላላቸው ሙከራዎች የሂደት ሪፖርቶች ለባለስልጣኑ በዓመት ሁለት ግዜ መቅረብ አለባቸው። የጥናት ጊዜያቸው ከአንድ አመት በታች ለሆኑት ሙከራዎች

submitted at the end of the period.	የመጨረሻው ሪፖርት በጥናቱ መጨረሻ ላይ መቅረብ አለበት፤
12) The sponsor or investigator shall have the duty to immediately notify the authority in case of an interruption in the clinical trial.	12. ስፖንሰር አድራጊው ወይም ተመራማሪው በህክምና ሙከራው ውስጥ መቋረጥ ሲያጋጥም ወዲያውኑ ለባለሥልጣኑ የማሳወቅ ግዴታ አለባቸው፤
13) The authority shall approve the final result of the clinical trial before dissemination and publication.	13. ባለ ሥልጣኑ የህክምና ሙከራው የመጨረሻ ውጤት ከመሰራጨቱ እና ከመታተሙ በፊት ማጽደቅ አለበት፤
14) Any serious adverse events identified shall be reported to the regulatory authority within 48 hours of the event's occurrence using the format in (Annex 5), irrespective of their causality association with the investigational product or procedure	14. ማንኛቸውም ተለይተው የታወቁት ከባድ የሆኑ አሉታዊ ክስተቶች ወይም የላብራቶሪ እክሎች ከምርምር ምርት ጋር ያላቸው ምክንያታዊ ግንኙነት ምንም ይሁን ምን ለተቆጣጣሪ ባለስልጣን ክስተቱ በተከሰተ በ48 ሰአታት ውስጥ በ(አባሪ 5) ውስጥ ያለውን ቅርጸት በመጠቀም ለተቆጣጣሪ ባለስልጣኑ ሪፖርት መደረግ አለባቸው፤
15) All other non-serious adverse events shall be reported monthly in a tabulated form (Annex 6).	15. ሌሎች ከባድ ያልሆኑ ሁሉም አሉታዊ ክስተቶች በየወሩ በሰንጠረዥ ፎርም (አባሪ 6) መሰረት ሪፖርት መደረግ አለባቸው፤
16. <u>Amendment to the Authorized Clinical Trial</u>	16. <u>ለተፈቀደ የህክምና ሙከራ ማሻሻያ</u>
1) The sponsor or investigator delegated by the sponsor shall apply to the authority and get authorization from the authority for any changes, variations, or amendments in the approved protocol or in any relevant clinical trial documents, including chemistry, manufacturing, and control.	1. ስፖንሰር ወይም ስፖንሰር አድራጊው የወከለው ተመራማሪ በተፈቀደው ፕሮቶኮል ወይም በማንኛውም ተዛማጅ የህክምና ሙከራ ሰነዶች፣ ኬሚስትሪ፣ ማምረት እና ቁጥጥርን ጨምሮ ማናቸውንም ለውጦች፣ ልዩነቶች ወይም ማሻሻያዎች ለማድረግ ለባለስልጣኑ ማመልከት እና ከባለስልጣኑ ፈቃድ ማግኘት አለበት፤

2) The Amendments shall be categorized as major and minor, and the requirements shall vary depending on the category of amendments. The sponsor or investigator representing the sponsor shall not implement major amendments to the approved clinical trial protocols or any relevant documents prior to approval by the authority.	2. ማሻሻያዎቹ ዋና እና ጥቃቅን ተብለው ይከፋፈላሉ፤ እንዲሁም መስፈርቶቹ እንደ ማሻሻያዎች ምድብ ይለያያሉ። ስፖንሰር አድራጊው ወይም ስፖንሰር አድራጊውን የሚወክለው ተመራማሪ በተፈቀደላቸው የህክምና ሙከራ ፕሮቶኮሎች ወይም አስፈላጊ ሰነዶች ላይ ዋና ማሻሻያዎችን በባለሥልጣኑ ከመጽደቁ በፊት መተግበር የለባቸውም፤
3) For minor amendments, the sponsor or investigator representing the sponsor may implement the proposed amendments immediately after proper categorization of the proposed amendments is confirmed in writing by the authority and clearance of administrative procedures.	3. ለጥቃቅን ማሻሻያዎች ስፖንሰር አድራጊው ወይም ስፖንሰር አድራጊውን የሚወክለው ተመራማሪ ያቀረበው የጥቃቅን ማሻሻያዎች ጥያቄ በትክክል ተፈርጆ በባለስልጣኑ በፅሁፍ ከተረጋገጠ እና አስተዳደራዊ ሂደቶች ከተጠናቀቁ በኋላ ወዲያውኑ ሊተገበር ይችላል፤
4) When there has been an amendment for clinical trials conducted in more than one site, the sponsor or applicant shall submit one complete amendment application to the authority.	4. ከአንድ በላይ ጣቢያዎች ላይ ለሚደረጉ የህክምና ሙከራዎች ማሻሻያ ሲደረግ፣ ስፖንሰሩ ወይም አመልካቹ አንድ የተሟላ የማሻሻያ ማመልከቻ ለባለስልጣኑ ማቅረብ አለባቸው፤
5) The application for the amendment shall include relevant information following Annex 4.	5. የማሻሻያ ማመልከቻው አባሪ 4ን ተከትሎ ጠቃሚ መረጃን ማካተት አለበት፤
6) The Authority shall review and give feedback for amendment applications within 15 working days.	6. ባለሥልጣኑ የማሻሻያ ማመልከቻዎችን በ15 የሥራ ቀናት ውስጥ ገምግሞ ግብረ መልስ መስጠት አለበት።
17. <u>Termination and Suspension of Clinical Trial</u>	**17.<u>የህክምና ሙከራ ማቋረጥ እና እገዳ</u>**

1) The authority may suspend or terminate a clinical trial, in its entirety or partially, at any time when it finds that the trial is non-compliant with the protocol, GCP principles, proclamation, guideline, or other requirements.	1. ባለሥልጣኑ በማንኛውም ጊዜ የህክምና ሙከራው ከፕሮቶኮሉ፣ ከመልካም የህክምና ሙከራ መርሆች፣ ከአዋጅ፣ ከአሰራር መመርያ ወይም ከሌሎች መስፈርቶች ጋር የማይጣጣም መሆኑን ሲያረጋግጥ የህክምና ሙከራውን ሙሉ በሙሉ ወይም በከፊል ሊያግድ ወይም ሊያቋርጥ ይችላል፤
2) When total or partial premature termination of a trial at a clinical trial site, notification prepared per annex 10 shall be given to the authority within 15 calendar days after the date of discontinuation.	2. በህክምና ሙከራ ቦታ ላይ ያለው ሙከራ በአጠቃላይ ወይም በከፊል ያለጊዜው ሲቋረጥ፣ ከተቋረጠበት ቀን አንስቶ ባሉት 15 ቀናት ውስጥ በአባሪ 10 መሰረት የተዘጋጀ ማስታወቂያ ለባለስልጣኑ መሰጠት አለበት፤
3) When the authority finds the reason for the termination of the CT is inadequate, regulatory measures shall be taken, and the sponsor shall be made to compensate the participants for the unnecessary exposure.	3. ባለሥልጣኑ የህክምና ሙከራው የተቋረጠበት ምክንያት በቂ አለመሆኑን ሲያረጋግጥ የቁጥጥር እርምጃዎች ይወሰዳሉ፤ እንዲሁም ስፖንሰር አድራጊው ተሳታፊዎች ላይ ለደረሰው አላስፈላጊ ተጋላጭነት ማካካሻ መክፈል አለበት፤
4) A clinical trial shall not be resumed once terminated by the authority or by the sponsor.	4. የህክምና ሙከራ በባለስልጣኑ ወይም በስፖንሰር አድራጊው ከተቋረጠ በኋላ እንደገና መቀጠል የለበትም፤
5) The authority may permit the continuation of the clinical trial suspended, in its entirety or at a site, when the sponsor present sufficient reasons and no changes are made to the study protocol or the chemistry, manufacturing, and control.	5. ስፖንሰር አድራጊው በቂ ምክንያቶችን ሲያቀርብ እና በጥናት ፕሮቶኮል ወይም በኬሚስትሪ፣ በአመራረት እና በመቆጣጠር ላይ ምንም አይነት ለውጥ ካልተደረገ፤ ባለሥልጣኑ ሙሉ በሙሉ ወይም በአንድ ቦታ የታገደው የህክምና ሙከራ እንዲቀጥል ሊፈቅድ ይችላል፤
18. <u>Clinical Trial Master File</u>	**18.<u>የህክምና ሙከራ ዋና ሰነድ</u>**

1) Any clinical trial shall have a trial master file which consists of the list of the following essential documents. A. Documents available before the start of the clinical phase of the study, B. Documents required to be collected/added during the conduct of the study, C. Documents must be collected after the completion or termination of the trial.	1. **ማንኛውም የህክምና ሙከራ የሚከተሉትን አስፈላጊ ሰነዶች ዝርዝር የያዘ የሙከራ ዋና ሰነድ ሊኖረው ይገባል።** **ሀ) ጥናቱ በሰው ልጅ ላይ ከመጀመሩ/ ከመካሄዱ በፊት ያሉ ሰነዶች፤** **ለ) ጥናቱ በሚካሄድበት ወቅት እንዲሰበሰቡ/እንዲጨመሩ የሚፈልጉ ሰነዶች፤** **ሐ) የህክምና ሙከራ ሂደቱ ከተጠናቀቀ ወይም ከተቋረጠ በኋላ ሊሰበሰቡ የሚገባቸው ሰነዶች፤**
2) The clinical trial master file shall be used to evaluate the clinical trial conduct and the quality of the data produced. The investigator and the sponsor have complied with the principles and guidelines of Good clinical practice and applicable requirements.	2. **የህክምና ሙከራ ዋና ሰነድ፤ የህክምና ሙከራ ትግበራውን እና የተገኘውን መረጃ ጥራት ለመገምገም ጥቅም ላይ ይውላል። ተመራማሪው እና ስፖንሰሩ የጥሩ ህክምናዊ ትግበራ መርሆዎችን እና መመሪያዎችን እንዲሁም የሚመለከታቸውን መስፈርቶች ማሟላት አለባቸው፤**
3) The trial master file shall provide the basis for the audit by the sponsor's independent monitor and for the inspection by the authority.	3. **የህክምና ሙከራ ዋና ሰነድ ከስፖንሰር አድራጊው ገለልተኛ ለሆነ ተቆጣጣሪ እና በባለስልጣኑ ለሚደረግ ቁጥጥር የምርመራ መሠረት ይሰጣል፤**
CHAPTER FIVE	**ምእራፍ አምስት**
INDEPENDENT ETHICS COMMITTEE AND CLINICAL TRIAL TEAM	**ነጻ የስነ ምግባር ኮሚቴ እና ህክምና ሙከራ ቡድን**
19. <u>Clinical Trial Ethics Review Committee Supervisory Body</u>	19)**የህክምና ሙከራ የሥነ-ምግባር ክለሳ/ ግምገማ ኮሚቴ የበላይ/ተቆጣጣሪ አካል**

1) The clinical Trial Ethics review committee supervisory body (hereinafter the supervisory body) has been established by this directive.	1. የህክምና ሙከራ የሥነ ምግባር ክለሳ/ ግምገማ ኮሚቴ ኮሚቴ ተቆጣጣሪ/የበላይ አካል (ከዚህ ቀጥሎ የበላይ አካል) በዚህ መመሪያ ተቋቁሟል
2) The director general of the authority shall chair the supervisory body.	2. የባለስልጣኑ ዋና ዳይሬክተር የበላይ አካሉን ይመራል።
3) The director general of the authority shall assign the members of the supervisory body.	3. የባለስልጣኑ ዋና ዳይሬክተር የበላይ አካል አባላትን ይመደባሉ።
4) The supervisory body shall have the following roles and responsibilities: A. Recognize the independent ethics committee established at an institutional, regional, or national level that reviews clinical trials conducted on human subjects. B. Monitor, supervise the activity, and provide guidance for independent ethics committees at all levels, C. Ensure the availability of independent ethics committess at all levels.	4. የበላይ አካል የሚከተሉትን ሚናዎች እና ኃላፊነቶች ይኖረዋል። ሀ) በሰው ልጆች ላይ የምደረጉ የሕክምና ሙከራዎችን ለምከልሱ በተቋም ፣ በክልል ወይም በአገር ደረጃ ተቋቋሙትን ለነፃ የሥነ ምግባር ኮሚቴዎች እውቅና ይሰጣል። ለ) በሁሉም ደረጃ ለሚገኙ ነጻ የሥነ ምግባር ኮሚቴዎች መመሪያ መስጠት፣ እንቅስቃሴዎቻቸውን መቆጣጠርና፣ መከታተል ሐ) በተለያየ ደረጃ ላይ ነፃ የሥነ ምግባር ኮሚቴዎችን መኖራቸዉን ያረጋግጣል።
5) The supervisory body shall ensure the absence of conflict of interest, including verifying the source of funding, competency, independence, and composition of an independent ethics committee.	5. የበላይ አካሉ የጥቅም ግጭት እንዳይከሰት የጥናቱን የገንዘብ ድጋፍ ምንጭ ፣ ነፃ የሥነ ምግባር ኮሚቴዉን ብቃት፣ ነፃነት፣ እና አወቃቀር ማረጋገጥን ጨምሮ ለሎች ሥራዎችን ይሠራል።
20. Independent Ethics Committee	20)ነጻ የስነ-ምግባር ኮሚቴ
1) There shall be an independent Ethics	1. የህክምና ሙከራ ተሳታፊዎችን መብት፣ ደህንነት እና የግል ሚስጥር መጠበቅን

Committee that reviews, approves a clinical application, and monitors the conduct of clinical trials that comply with ethical principles such as protecting the rights, welfare, and privacy of trial participants.	**የመሳሰሉ ከሥነ ምግባር መሠረታዊ መሪህሆች ጋር የሚጣጣሙ የህክምና ሙከራዎችን አካሄድ የሚመረምር፣ የሚያጸድቅና የሚከታተል ነጻ የሥነ ምግባር ኮሚቴ ይኖራል።**
2) The independent ethics committee's composition shall have members with professional competency, research ethics training, and experience balanced regarding relevant expertise, gender, age, and community representation.	2. **የነጻ የሥነ፡ምግባር ኮሚቴ አወቃቀር ብቃት ያላቸዉ ባለሞያዎች፣ የምርምር ሥነ፡ምግባር ስልጠና ያላቸው አባላት፣ እና አግባብ ያለው ክህሎትን ጨምሮ፣ ሚዛናዊ የፆታ፣ የዕድሜ፣ እና የማህበረሰብ ወኪል አባላቶች ይኖራቸዋል።**
3) The committee shall be independent of the investigator, the sponsor, or any other kind of undue influence.	3. **ኮሚቴው ከተመራማሪው፣ ከስፖንሰሩ ወይም ከማንኛውም ዓይነት ተገቢ ያልሆነ ተፅዕኖ ነፃ መሆን አለበት።**
4) The committee shall have the following power and duties: a. Approve or modify the application of clinical trial in perspective ethical compliance; b. Monitor the conduct of the clinical trial to ensure that it complies with the ethical requirements; or c. Notify measures taken on noncompliance to the authority and may withdraw its approval.	4. **ኮሚቴው የሚከተለው ሥልጣንና ግዴታ ይኖረዋል**: **ሀ) ከሥነ ምግባር መሪህዎች አኳያ የህክምና ሙከራ ማመልከቻው ተግባራዊ እንድደረግ ይፈቀዳል ወይም ያሻሽላል።** **ለ) ከሥነ ምግባር መሥፈርቶች ጋር እንዲስማማ ለማድረግ የህክምና ሙከራውን አካሄድ ይከታተላል፤ ወይም** **ሐ) የሥነ ምግባር መሥፈርቶችን አለማክበርን/ጥሰትን በተመለከተ የተወሰዱ እርምጃዎችን ለባለ ሥልጣኑ ማሳወቅ ና**

	የሕክምና ሙከራ ፈቃድን ሊያሳጣም ይችላል
5) An Independent National Ethics Committee shall review clinical trials under the following conditions: a. In the absence of a recognized Independent Ethics Committee within the institution where the trial is conducted b. Where the Independent Ethics Committee unable to perform the ethical review activities according to the standards c. The clinical trial is conducted in more than one site or multi-center trial.	5. ነፃ ብሔራዊ የሥነ ምግባር ኮሚቴ በሚከተሉት ሁኔታዎች ሥር የህክምና ሙከራዎችን ይከልሳል: ሀ) የሕክምና ሙከራዉ በሚካሄድበት ተቋም ውስጥ እውቅና ያገኘ ነጻ የስነ ምግባር ኮሚቴ ሳይኖር ለ)ነጻ የስነ፡ምግባር ኮሚቴዉ በመስፈርቱ መሰረት የስነ ምግባር ክለሳ እንቅስቃሴዎችን ማከናወን ሳይችል ስቀር ሐ) የሕክምና ሙከራው ከአንድ በላይ ቦታ ላይ ወይም ባለ ብዙ ማእከል ሙከራ ስሆን
21. Roles and Responsibilities of a Sponsor or an Applicant	**21)የስፖንሰር ወይም የአመልካች ድርሻና ኃላፊነት**
1. The sponsor shall be primarily responsible for the following: A. Designing the clinical trial B. Developing the study protocol, investigator's brochure, and related materials to describe the procedures that will be followed, study endpoints, data collection tools, and other study requirements, C. Ensuring that the protocol complies with applicable national and local laws and regulations D. Establish an independent data safety	1) ስፖንሰሩ በዋናነት ለሚከተሉት ተጠያቂ ይሆናል፡ ሀ) የሕክምና ሙከራዉን ይነደፋል ወይም ዲዛይን ያደርጋል ለ) የሚከተሉትን አሰራሮች፣ የጥናት መጨረሻ ነጥቦች፣ መረጃ የመሰብሰብ መሳሪያዎች፣ እና ሌሎች የጥናት መስፈርቶች የምገለጽ የጥናት ፕሮቶኮል፣ የተመራማሪውን ብሮሹር እና ተዛማጅ የሆኑ ቁሳቁሶችን ማዳበር ሐ) ፕሮቶኮሉ ተፈጻሚነት ያላቸዉ ብሔራዊና የአካባቢ ሕጎችንና ደንቦችን የሚከተል መሆኑን ማረጋገጥ። መ) መተዳደሪያ ቻርተር ያለዉ ና ተገቢ ብቃት ያላቸው በቂ አባላትን የያዘ የመረጃ ደህንነት

monitoring board with its charter and adequate members with appropriate qualifications and notify the authority.	ክኾል ቦርድ አቋቁሞ ለባለስልጣኑ ማሳወቅ።
2. The sponsor may delegate any or all the trial-related functions to another person. However, in such cases, the sponsor shall remain responsible for ensuring that the conduct of the trials and the final data generated by those trials comply with the approved protocol and relevant law, including this directive.	2) ስፖንሰሩ ከህክምና ሙከራው ጋር የተያያዙ ተግባራትን በከፍል ወይም በሙሉ ለሌላ ሰው ሊሰጥ ይችላል።ይሁን እንጂ እንዲህ ዓይነት ሁኔታዎች በሚያጋጥሙበት ጊዜ የሕክምና ሙከራ ና ከሕክምና ሙከራዎች የሚያገኘዉ የመጨረሻ መረጃ ይህን መመሪያ ጨምሮ ተቀባይነት ካገኘው መመሪያና ተያያዥነት ካላቸው ሕግ ጋር እንዲስማማ የማድረግ ኃላፊነት አለበት ።
3. The sponsor shall ensure that the trial site team is adequately trained and qualified, a quality management system is employed, a monitor is assigned, and insurance is available for the conduct of the trial.	3) ስፖንሰሩ የህክምና ሙከራ ቦታ ቡድን በበቂ ሁኔታ የሰለጠነና ብቃት ያለው መሆኑን፣ የጥራት የአስተዳደር ሥርዓት መዘርጋቱን፣ ሞኒተር መመደቡን ና ለህክምና ሙከራው ኢንሹራንስ መኖሩን ማረጋገጥ አለበት።
4. The investigator and the sponsor shall establish written agreement on the protocol, the monitoring, the auditing, and on standard operating procedures, and the allocation of adequate budget and trial-related responsibilities before the commencement of the trial.	4) ተመርማሪውና ስፖንሰሩ በፕሮቶኮል፣በክትትል ህደቱ፤ ኦዲቲንግና በመደበኛ የአሠራር ሂደቶች ላይ እንዲሁም በቂ በጀት መመደቡን ና ከህክምና ሙከራው ጋር የተያያዙ ኃላፊነቶችን በተመለከተ የሕክምና ሙከራው ከመጀመሩ በፊት በጽሑፍ የሰፈረ ስምምነት ልኖራቸው ይገባል።
5. The sponsor or the applicant shall notify the authority when a clinical trial is completed or interrupted, or a clinical trial site is closed.	5) ስፖንሰር ወይም አመልካች የህክምና ሙከራው ሲጠናቀቅ ወይም ሲቋረጥ ወይም የህክምና ሙከራው ቦታ ሲዘጋ ለባለስልጣኑ

	ማሳወቅ አለበት።
6. The sponsor or the applicant shall ensure that the investigational product(s) is: A) Characterized as appropriate to the stage of development of the product(s), B) Adequately available, C) Manufactured following current good manufacturing practices, D) Reconciliation and destruction/ disposal are performed appropriately.	6) ስፖንሰር ወይም አመልካች ለምርምር የምውለው መድኃኒት/ቶች የምከተሉትን ማሟላታቸውን ማርጋገጥ አለበት። ሀ) ለምርቱ የዝግጅት ህደት ደረጃ ተገቢነት ያለው መሆኑን፣ ለ) በበቂ መጠን መገኘቱን፣ ሐ) አሁን ያለዉን ጥሩ የአመራረት ህደትን ተከትሎ የተመረተ መሆኑን፣ መ) ለህክምና ሙከራ የዋለው መድሃንት እራሱ መሆኑንና በአግባቡ መወገዱን።
7. The sponsor or the applicant shall be responsible for submitting amendments to the authority prior to implementing such amendments in the conduct of the clinical trial.	7) ስፖንሰር ወይም አመልካች በህክምና ሙከራው አካሄድ ላይ ማሻሻያዎች ብደርጉ ማሻሻያዎቹ ከመተግበራቸው በፊት ለባለስልጣኑ የማሳወቅ ሃላፊነት አለበት።
8. The sponsor or the applicant, or a principal investigator shall report to the authority when any adverse events occur in the trial and adverse event that occurs in another trial	8) ስፖንሰሩ ወይም አመልካቹ ወይም ዋና መርማሪ በሙከራ ሂደቱ ውስጥ እና በሌላ ሙከራ ውስጥ የተከሰቱ አሉታዊ ክስተቶች ሲከሰቱ ለባለስልጣኑ ሪፖርት ማድረግ አለባቸው።
9. The sponsor or the applicant shall ensure that the auditing of clinical trials/systems is conducted following the sponsor's written plans and procedures on what to audit, how to audit, the frequency of audits, and the form and content of audit reports.	9) ስፖንሰር ወይም አመልካች የህክምና ሙከራዎቹ ወይም ስርዓቶቹ ኦዲት፥ ምን ኦድት መገረግ እንደለበት፣ እንዴት ኦዲት መደረግ እንዳለበት፣ የኦዲት ድግግሞሽ፣ እንዲሁም የኦዲት ሪፖርቶች ቅጽ እና ይዘት ላይ የስፖንሰሩ የጽሁፍ እቅድና አሰራርን ተከትሎ መከናወኑን ማረጋገጥ አለበት ።
10. The sponsor or the applicant shall establish a recording system and ensure the trial subjects'	10)ስፖንሰር ወይም አመልካች የመረጃ አያያዝ ስርዓትን ማቋቋም እንዲሁም የህክምና ሙከራው ተሳታፊዎችን ምስጢራዊነት

confidentiality.	ማረጋገጥ አለበት።
11. The sponsor or the applicant shall retain essential documents at least ten years after the formal discontinuation of clinical development of the investigational product.	11)ስፖንሰር ወይም አመልካች ምርምሩ በመደበኛነት ከቋረጠ በኋላ አስፈላጊ ሰነዶችን ቢያንስ እስከ አምስት ዓመት ማስቀመጥ አለበት።
12. The sponsor or the applicant shall provide a periodic, interim, and final report of the clinical trial according to the specified timelines in the approved protocol and this directive	12)ስፖንሰር ወይም አመልካች በተፈቀደለት ፕሮቶኮልና በዚህ መመሪያ ላይ በተቀመጠው የጊዜ ሰሌዳ መሰረት በየጊዜው፣ ጊዜያዊና የመጨረሻ ሪፖርት ማቅረብ አለበት።
13. The sponsor or the applicant shall know that depending on the type of clinical trial, the authority may not allow remote or central monitoring.	13)ስፖንሰሩ ወይም አመልካቹ እንደ ህክምና ሙከራው ዓይነት ባለስልጣኑ የርቀት ወይም ማዕከላዊ ክትትል ሊፈቅድም ላይፈቅድም እንደሚችል ማወቅ አለበት።
14. The sponsor retains trial-related duties and functions not explicitly transferred to the contract research or organization.	14)ስፖንሰር አድራጊው ለኮንትራት የምርምር ተቋም ወይም ድርጅት በግልፅ ያልተላለፉ ከሙከራው ጋር የተያያዙ ግዴታዎች እና ተግባራትን ይዞ ይቆያል።
22. Roles and responsibilities of the principal investigator	22.የህክምና ሙከራው ዋና መርማሪ ኃላፊነትና ግዴታ
A) To ensure that a registered and licensed pharmacist maintains appropriate records of the product's delivery to the trial site, the inventory at the site, the use by each trial participant, and the return to the sponsor or alternative disposition of unused	ሀ)የተመዘገበና ፈቃድ ባለው ፋርማሲስት የህክምና ሙከራው የሚደረግበት መድኃኒት ሙከራው ወደሚደረግበት ተቋም የተወሰደበትን፣ በእያንዳንዱ የህክምና ሙከራው ተሳታፊ ላይ ጥቅም ላይ መዋሉን፣ ጥቅም ላይ ያልዋለ ሙከራው የሚደረግበት መድኃኒት ወደ ህክምና ሙከራው ደጋፊ አካ መመለሱን ወይም

product(s).	መወገዱን የሚያሳውቁ አግባብ ያላቸው መረጃዎች በተመዘገበና ፈቃድ ባለው ፋርማሲስት በአግባቡ መያዛቸውን ማረጋገጥ
B) Keep a record of all documents, including records that show participants were provided the doses specified by the protocol and reconciliation of all investigational products.	ለ) ለጥናት የተጠቀሙባቸውን መድኃኒቶች ጥቅም ላይ የዋሉትና ያልዋሉት ተለይተው የታረቁበትንና የተመዘገቡበትን ሰነድ እንዲሁም የመድኃኒት ሙከራው ለተካሄደባቸው ሰዎች መድኃኒቱ በትክክል ፕሮቶኮሉ ላይ እንደተቀመጠው እንደተሰጣቸው የሚያረጋግጠውን መረጃ በአግባቡ አደራጅቶ መያዝ
C) To ensure the confidentiality of all records related to the clinical trial activity	ሐ) ማንኛውንም የህክምና ሙከራውን ስራ በሚመለከት የተያዙ ሰነዶችን ምስጢራዊ አጠባበቅ ማረጋገጥ
D) To maintain a list of appropriately qualified study team members to whom the investigator has delegated significant trial-related duties	መ) የህክምና ሙከራ መርማሪው የህክምና ሙከራውንና ተያያዥ ስራዎችን ይሰሩልኛል ብሎ የሰየማቸውን ተገቢና ብቁ የጥናቱ ቡድን አባላት ዝርዝር አደራጅቶ መያዝ
E) To permit monitoring and auditing by the sponsor and inspection by the authority.	ሠ)የህክምና ሙከራውን በሚመለከት ጥናቱን በገንዘብ የደገፈው አካል ቁጥጥር እና ክትትል ባለስልጣኑ ደግሞ ፍተሻ እንዲያካሂዱ መፍቀድ
F) To carry out its responsibility in pharmacovigilance throughout the conduct of the clinical trial through the recording of all adverse events (AE), including abnormal laboratory results, as instructed in the protocol; reporting to the sponsor all serious adverse events (SAE); providing follow-up reports of SAEs, and any other information requested, within the time frame identified in the protocol.	ረ) የህክምና ሙከራው በሚሰራበት ወቅት የመድኃኒት ጎጂ ባህርያት ክትትልን ፕሮቶኮሉ ላይ በተቀመጠበት አግባብ ተግባራዊ በማድረግ ሀላፊነትን መወጣት ሀላፊነቶቹም፤ ማንኛውንም ከፍተኛ የመድኃኒት ጎጂ ክስተት እንዲሁም ያልተለመደ የላቦራቶሪ ውጤትን ጨምሮ ፕሮቶኮሉ ላይ በተቀመጠው መሰረት መዝግቦ መያዝ፣ ስለከፍተኛ ጎጂ ክስተቱ ለምርምሩ ደጋፊ አካል ማሳወቅ፣በከፍተኛ ጎጂ ክስተቱ ላይ የተደረገውን ክትትል ሪፖርት ማቅረብ፣እንዲሁም ሌሎች የሚጠየቁ መረጃዎችን ፕሮቶኮሉ ላይ በተወሰነው የጊዜ ማእቀፍ መሰረት ማቅረብ ይሆናሉ.
G) Submit written summaries of the progress report of the trial status to the authority bi-annually or	ሰ)የህክምና ሙከራው ስራ የደረሰበትን ደረጃ በሚመለከት በአመት ሁለት ጊዜ ወይም ጥያቄ ከቀረበ ወቅት ከዚያም በፊጠነ ጊዜ የማጠቃለያ

more frequently, if requested.	ጽሁፍ ማቅረብ
H) To document all refusals and withdrawals and shall ensure that no data for the clinical trial are collected from participants that refuse to participate in or have withdrawn from the clinical trial.	ሸ)የህክምና ሙከራው ተሳታፊዎች የህክምና ሙከራው ላይ ላለመሳተፍ የወሰኑበትን እና ጥናቱን ትተው ከወጡ ደግሞ የወጡበትን መረጃ በአግባቡ ሰንዶ መያዝ እንዲሁም ምንም አይነት መረጃ ከእነዚህ ተሳታፊዎች ተሰብስቦ በህክምና ሙከራው ውስጥ እንዳይካተት ማረጋገጥ
2) The investigator shall be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current investigator's brochure, product information, and other sources provided by the sponsor.	2)የህክምና ሙከራው መርማሪ ለጥናቱ የሚጠቀምባቸውን መድኃኒቶች፣ ፕሮቶኮሉ ላይ እንደተቀመጠው፣ ወቅታዊ የምርመራው ማስታወቂያ በራሪ ወረቀት እንደሚያሳው፣ የሚሞከረው መድኃኒት መረጃ እንደሚያስገነዝበው እንዲሁም ሌሎች በደጋፊው አካል የቀረቡ መረጃዎች እንደሚያስገነዝቡት ስለሚሞከረው መድኃኒት አግባባዊ አጠቃቀም በደንብ ማውቅ ይኖርበታል
3) The investigator shall know and comply with good clinical practice and applicable regulatory requirements.	3))የህክምና ሙከራው መርማሪ የመልካም የህክምና ሙከራ አሰራርንና ሌሎች ተገቢ የቁጥጥር መስፈርቶችን ማወቅና ተግባራዊ ማድረግ ይኖርበታል
4) The investigator shall only unblind a participant's treatment allocation during a clinical trial if unblinding is relevant to the participant's safety.	4))የህክምና ሙከራው መርማሪ የሙከራው መድኃኒት በአንድ የህክምና ሙከራ ተሳታፊ ላይ የሚሞከርበትን ምስጢራዊ አመዳደብ መግለጽ የሚችለው መድኃኒቱ የተሞከረበት ሰው በጤናው ላይ የደህንነት ስጋት በሚያጋጥመው ወቅት ብቻ ነው
23. Roles and Responsibilities of the Contract Research Organization	23) የኮንትራት ምርምር ድርጅት ሀላፊነትና ግዴታ
1) The contract research organization shall undertake activities delegated by the sponsor and be accountable together with the sponsor for any noncompliance or fault.	1)የኮንትራት ምርምር ድርጅቱ ማንኛውንም የምርምሩ ደጋፊ አካል እንዲሰራ የወከለውን ስራ የሚሰራ ሲሆን ለማንኛውም በህክምና ሙከራው ላይ ለሚከሰት ህግና ስርአት ያለመከበር ወይም ጥፋት ከደጋፊው አካል ጋራ በጋራ ተጠያቂ ይሆናል
2) Any trial-related duty and function transferred	2)ማንኛውም የህክምና ሙከራ ላይ በኮንትራት

to and assumed by a contract research organization shall be specified in a written agreement.	ምርምር ድርጅት እንዲሰራ የተላለፈና እንዲተገበር የታሰበ ስራ ወይም ግዴታ በጽሁፍ ስምምነት የተደረገ መሆን አለበት
3) All references to a sponsor in this directive also apply to a contract research organization to the extent that the contract research organization has assumed a sponsor's trial-related duties and functions.	3) የኮንትራት ምርምር ድርጅቱ ህክምና ሙከራውን በሚመለከት የህክምና ሙከራ ደጋፊ አካሉን ስራዎችና ግዴታዎች እስከተቀበለ ድረስ በዚህ መመሪያ ላይ የተጠቀሱት ነጥቦች በሙሉ የኮንትራት ምርምር ድርጅቱ ላይም ተግባራዊ ይሆናሉ
24. Roles and responsibilities of the monitor	24) የተቆጣጣሪው ኃላፊነትና ግዴታዎች
1) A monitor shall be appointed by the sponsor, appropriately trained, and have the adequate scientific and clinical knowledge to monitor the trial.	1)የህክምና ሙከራ ተቆጣጣሪው በህክምና ሙከራው ደጋፊ አካል የሚመረጥ ሲሆን፤ ተገቢውን ስልጠና የወሰደና ህክምና ሙከራውን ለመቆጣጠር በቂ ሳይንሳዊና የህክምና እውቀት ያለው መሆን አለበት
2) A monitor shall be thoroughly familiar with the investigational product(s), the protocol, the written informed consent form, and any other written information to be provided to participants, the sponsor's standard operating procedures, good clinical practice, and the applicable regulatory requirement(s). The monitor shall be responsible:	2) ተቆጣጣሪው፤ ጥቅም ላይ ስለሚውለው የሙከራ መድኃኒት፣ስለፕሮቶኮሉ፣ ለተሳታፊዎች ስለሚሰጠው የጽሁፍ የስምምነት ፎርም፣ለተሳታፊዎች ስለሚሰጥ የተጻፈ መረጃ፣ የስፖንሰሩ መደበኛ የአሰራር ስርአት ቅደም ተከተሎች፣ ስለ ጥሩ ህክምና ሙከራ ትግበራ እንዲሁም ስለ ተግባራዊ የቁጥጥር መስፈርቶች በቂ እውቀት ሊኖረው የሚገባ ሲሆን በህክምና ሙከራው ወቅት የሚከተሉት ሀላፊነቶች ይኖሩታል
A) To protect the rights and well-being of human participants.	ሀ) የህክምና ሙከራውን ተሳታፊዎች መብትና ደህንነት መጠበቅ
B) To ensure the reported trial data are accurate, complete, and verifiable from source documents.	ለ) የተገኘው የህክምና ሙከራ መረጃ ትክክለኛ፣የተሟላና በመነሻ መረጃዎች መረጋገጥ የሚችል መሆን አለበት
C) To ensure the conduct of the trial complies	ሐ)የህክምና ሙከራው አሰራር በወቅቱ በጸደቀው

with the currently approved protocol and amendment, with good clinical practice, and with the applicable regulatory requirement.	ፕሮቶኮል ወይም ማሻሻያው መሰረት፣ በጥሩ የህክምና ሙከራ አተገባበር እንዲሁም ተግባራዊ ቁጥጥር መስፈርቶች መሰረት እየተካሄደ እንደሆነ ማረጋገጥ
3) The extent and nature of monitoring shall be determined by the sponsor and stated in the protocol or in the monitoring plan.	3)የሚደረገው ቁጥጥር ስፋቱና አይነቱ በህክምና ሙከራው ደጋፊ አካል ይወሰንና በፕሮቶኮሉ እና በክትትል እቅዱ ላይ ይገለጻል
25. Data and Safety Monitoring Board	25) የመረጃና ደህንነት ተቆጣጣሪ ቦርድ
1)Data and Safety Monitoring Board shall be responsible for assessing a clinical trial's progress at intervals, the safety data, and the critical efficacy endpoints, and for recommending to the sponsor whether to continue, modify, or stop a trial.	1)የመረጃና ደህንነት ተቆጣጣሪ ቦርድ ሀላፊነቶች በተወሰኑ ጊዜዎች የህክምና ሙከራውን አካሄድ መመርመር፣ የደህንነቱ መረጃና ወሳኙን የውጤታማነት ክስተቶች መገምገም፣ ለህክምና ሙከራው ደጋፊ አካል የህክምና ሙከራውን እንዲቀጥል፣ ማስተካከያ እንዲያደርግ ወይም እንዲያቋርጥ ምክረሀሳብ ማቅረብ ናቸው
2. Data and Safety Monitoring Board shall be independence with clearly indicated roles and responsibilities.	2)የመረጃና ደህንነት ተቆጣጣሪ ቦርድ ነጻና ሀላፊነትና ግዴታዎቹ በግልጽ የተቀመጡ መሆን አለባቸው
CHAPTER SIX **MONITORING AND GOOD CLINICAL PRACTICE INSPECTION**	**ምእራፍ ስድስት** **ቁጥጥርና መልካም የህክምና ሙከራ ፍተሻ**
26. Monitoring and Inspection	26) ቁጥጥርና ፍተሻ
1) The authority shall monitor that the sponsor, investigator, contract research organization, or research centers comply with the good clinical practice principle, protocol, applicable regulations and SOPs	1) ባለስልጣኑ፣ የህክምና ሙከራው ደጋፊ አካል፣ የህክምና ሙከራ መርማሪው፣ የኮንትራት ምርምር ድርጅቱ ወይም የጥናት ማእከላት የመልካም የህክምና ሙከራ ትግበራ መርሆዎችን፣ ፕሮቶኮሉን እንዲሁም ተግባራዊ የሆኑ የቁጥጥር ደንቦችንና የአሰራር ስርአቶችን አክብረው መስራታቸውን ይቆጣጠራል
2) The authority shall perform good clinical	2) ባለስልጣኑ የህክምና ሙከራው ከመጀመሩ

practice inspections before the commencement of the trial, during the conduct, and after completion of the trial and triggered as necessary. Sudden inspection may or may not be notified to principal investigator/the site.	በፊት፣ እየተካሄደ እያለ፣ ወይም ሙከራው ከተጠናቀቀ በኋላ፣ ወይም በማንኛውም አስፈላጊ ወቅት በሁኔታዎች አነሳሽነት በድንገት የሚካሄድ የመልካም ህክምና ሙከራ ትግበራ ፍተሻዎችን እንደአስፈላጊነቱ ያካሂዳል በድንገት ሊካሄድ ስለሚችለው ፍተሻ የህክምና ሙከራው ዋና ተቆጣጣሪ ወይም የሚካሄድበት ተቋም ላይነገረው ይችላል
3) The authority shall assign two or more experts to conduct onsite GCP inspection. When necessary, the authority may invite external experts to conduct inspections with clear binding procedures.	3) ባለስልጣኑ የመልካም ህክምና ሙከራ ትግበራ ፍተሻዎችን ለማካሄድ ሁለት ወይም ከዚያ በላይ ባለሙያዎችን ይመድባል እንደአስፈላጊነቱም ይህንን ስራ ለማሰራት ከመስሪያ ቤቱ ውጭ የሚገኙ ባለሙያዎችን ግልጽና አስገዳጅ አሰራር ስርአቶችን አዘጋጅቶ በመጋበዝ የፍተሸ ስራውን ያሰራል
4) The authority shall monitor the clinical trial site in terms of fulfilling the minimum requirements a clinical trial site, which includes; containing adequate rooms for waiting areas, participant screening, provision of education on the clinical trial and delivery of consent, drug administration, laboratory, admission in case of a bioequivalence study and appropriate setup for providing medical care and managing emergencies	4) ባለስልጣኑ የህክምና ሙከራ የሚካሄድባቸውን ተቋማት በሚቆጣጠርበት ወቅት ተቋማቱ ዝቅተኛውን የእጅግ በጣም ጥሩ የህክምና ሙከራ ተቋም መስፈርት ማሟላታቸውን ለማረጋገጥ ለተሳታፊዎች፤ በቂ የመቆያ፣ለህክምና ሙከራው ተገቢ መሆናቸውን የመፈተሻ፣ ስለህክምና ሙከራው ትምህርት የሚሰጥበት፣ በህክምና ሙከራው ለመሳተፍ ስምምነታቸውን የሚሰጡበት፣ የሙከራ መድኃኒቱን የሚወስዱበት፣ የላቦራቶሪ፣ ባዮኢኩቫለንስ የሚሰራ ከሆነ የሚተኙበት ክፍልና በህክምና ሙከራው ወቅት ለሚያጋጥሙ ድንገተኛ ህመሞች ህክምና የሚሰጥበት ተገቢው ዝግጅት መኖሩን ይቆጣጠራል
5) As applicable the principal investigator, co-investigators, study coordinator, lab personnel, and a pharmacist shall be present during the inspection.	5) በፍተሻው ወቅትም እንደአግባብነቱ፤ ዋና ተቆጣጣሪው፣ ረዳት ተቆጣጣሪዎች፣ የጥናቱ አስተባባሪዎች፣ የላቦራቶሪ ሰራተኞች እና ፋርማሲስት መገኘት ይኖርባቸዋል
6) All essential documents, including source documents, shall be made available during an inspection.	6) በፍተሻ ወቅት መነሻ ሰነዶችን ጨምሮ ከህክምና ሙከራው ጋር የተያያዙ ሁሉም አስፈላጊ ሰነዶች መቅረብ ይኖርባቸዋል

.7) The authority shall maintain a list of records of inspections, including the good clinical practice compliance status and their follow-up.	7) ባለስልጣኑ ህክምና ሙከራውን በሚመለከት የተደረጉ የመልካም ህክምና ሙከራ ትግበራዎች አከባበር ያለበትን የአፈጻጸም ደረጃ እና የተደረገውን ክትትል እንዲሁም የተካሄዱ ፍተሻዎችን ዝርዝር አሰናድቶ ይይዛል
27. Inspection Results	27) የህክምና ሙከራ ፍተሻ ውጤቶች
1) The authority shall issue an inspection report within 15 calendar days of conducting the inspection.	1) ባለስልጣኑ ፍተሻውን ባካሄደበት እስከ 15 ቀን ባለው ጊዜ የፍተሻ ሪፖርት ያዘጋጃል
2) Once the authority notifies the sponsor regarding the finding of the inspection, the sponsor shall take corrective and preventive action within 15 days of receiving the report	2) ባለስልጣኑ የህክምና ሙከራ ደጋፊ አካሉን ስለፍተሻው ውጤት ካሳወቀ በኋላ፣ ደጋፊ አካሉ ሪፖርቱን በተቀበለ በ15 ቀን ውስጥ የማስተካከያ እና የመከላከያ እርምጃ ይወስዳል
3) Regulatory measures to be taken after inspection shall depend on the category of the findings which may vary as critical, major, and minor findings	3)ከፍተሻው በኋላ የሚወሰዱ የቁጥጥር እርምጃዎች እንደ ፍተሻ ግኝቱ የሚወሰኑ ሲሆን ግኝቶቹ ወሳኝ፣ከፍተኛ ወይም አነስተኛ ሊሆኑ ይችላሉ.
4) Critical findings shall result in the suspension or termination of the clinical trial.	4)የፍተሻ ግኝቱ ወሳኝ ከሆነ የህክምና ሙከራው ሊታገድ ወይም ሊቋረጥ ይችላል
5) The authority may conduct inspections jointly with other countries for multi-country trials.	5) ከአንድ በላይ ሀገር ላይ ለሚካሄዱ የህክምና ሙከራዎች ባለስልጣኑ ከሌሎች ሀገራት ጋር በመጣመር የህክምና ሙከራ ፍተሻ ሊያካሂድ ይችላል
CHAPTER SEVEN	ምዕራፍ ሰባት

MISCELLANEOUS PROVISIONS	ልዩ ልዩ ድንጋጌዎች
28. Transitional Provision All clinical trials authorized or started operation before the effective date of this directive shall be subjected to this directive for the remaining activities of the clinical trial.	**28. የሽግግር አንቀጽ** **ይህ መመሪያ ከመጽደቁ በፊት ፈቃድ የተሰጣቸው ወይም ትግበራ የጀመሩ የህክምና ሙከራዎች ሁሉ ለቀሪው ስራቸው መመሪያው ላይ የተጠቀሱት ድንጋጌዎች ተግባራዊ ይደረጉባቸዋል**
29. Effective Date This directive shall be effective since April 13/2023, approved by the Authority.	29. **መመሪያው የሚጸናበት ቀን** **ይህ መመሪያ በባለስልጣኑ ከጸደቀበት ከሚያዝያ** 5/2015 **ዓ.ም ጀምሮ የጸና** **ይሆናል።።**
Heran Gerba Director General, Ethiopian Food and Drug Authority	**ሄራን ገርባ** **የኢትዮጵያ ምግብና ቁጥጥር ባለስልጣን ዋና ዳይሬክተር**

ANNEXURES

Annex 1 List of documents to be submitted for a clinical trial authorization application

No	ITEM
1.	□ Cover later, including the list of documents submitted and their version number and date
2.	□Completed clinical trial application form, including cover page
3.	□Clinical trial protocol,including site-specific addendums
4.	□Informed consent forms(s)
5.	□ Product information if the investigational medical product is registered: Summary of product characteristics, patient information leaflet/package Insert,and labeling
6.	□ Investigator's brochure; investigational supplies accountability forms.
7.	□If applicable, a synopsis of previous trials with the investigational medical product(s)
8.	□If applicable, electronic copies of key peer-reviewed publications following ICNJE recommendations to support the application
9.	□Copy/ies of recruitment advertisement(s) if applicable and questionnaires
10.	□Investigational medical product dossier[1](if applicable)
11.	□Product information and certificate of analysis for the concomitant and rescue medications applicable
12.	□GMP certificate for IMP(s)[2]from country of origin
13.	□Certificate(s) of analysis of the IMP(s)
14.	□Certificate(s) of accreditation for the central laboratories, if applicable
15.	□Signed declaration by the applicant
16.	□Singed declaration by the national principal investigator
17.	□Workload forms for the investigators
18.	□Signed curriculum vitaefor all clinical trial study teams participating in the clinical trial, eg principal investigator, co-investigator, study coordinator,and monitor….
19.	□Signed joint financial declaration between the sponsor and the principal investigator
20.	□Adverse event or safety reporting forms.
21.	□Signature logs; case report forms (CRFs);

22.	□Formats for progress reports, annual reports, and final study reports;
23.	□Informed consent documents.
24.	□ Insurance certificate for study participants
25.	□Proof sponsor indemnification for investigators and the trial site
26.	□GCP training certificates for all clinical trial team members
27.	□Proof of registration of the key investigators with a professional statutory body
28.	□Proof of professional indemnity (malpractice insurance)
29.	□ Study budget breakdown
30.	□ Certificate(approval) of independent ethics committee
31.	□Data Safety Monitoring Board charter and composition(where applicable)

1) *This is not required if the investigational medical product was granted registration by a stringent regulatory authority and will be used as defined therein, or if the investigational medical product is prequalified by the WHO.*
2) *Investigational medical product and placebo*

Annex 2: Contents of a clinical trial documents to be submitted

2.2. Application form **to be filled by the applicant**

Section 1: Trial identification	
Countries to which the application is submitted	
Trial's title	
Trial's short title where available	
Protocol number, date, and version	
Phase of the trial	
If applicable: international trial identifiers: WHO, clintrials.gov, EudraCT, etc	
Section 2: Regulatory details	

Name other Regulatory Authorities or Ethics Committees to which this application has been submitted, and/or approved.	
If applicable, explain why the trial is not going to be conducted in the host country of the applicant/sponsor.	
If applicable, name other Regulatory Authorities or Ethics Committees that have rejected this trial and explain.	
If applicable, provide details and explain why this trial was halted at any stage by other Regulatory Authorities.	
Section 3: Identification of the sponsor responsible for the application	
Sponsor	
Name of the organization	
Name of the contact person	
Address	
Telephone number	
Fax number	
E-mail	
Sponsor's legal representative in the countries where approval is sought.	
Name of the organization	
Name of the contact person	
Address	

Telephone number	
Fax number	
E-mail	
Sponsor status	
Commercial	
Non-commercial	
Section 4: Applicant identification	
State who is submitting the application: sponsor, sponsor's legal representative or person/organization authorized by the sponsor to submit the application.	
Name of the organization	
Name of the contact person	
Address	
Telephone number	
Fax number	
E-mail	
Section 5: Investigators' details	
Principal Investigator (if applicable)	
Name	
Qualification (MD, dentist, other)	
Professional address	
Telephone number	

Fax number	
E-mail	
National principal investigator (if applicable)	
Name	
Qualification (MD, dentist, other)	
Professional address7	
Telephone number	
Fax number	
E-mail	
Co- investigator (s) (if applicable)	
Name	
Qualification(MD, dentist, other)	
Professional address7	
Telephone number	
Fax number	
E-mail	
Monitor	
Name	
Address	
Telephone number	
Fax number	
E-mail	

Section 6: Details of trialists and sites	
Details of the site(s): name, physical address, contact details, contact person including telephone and email contacts	
Details on the study team including number, names, qualifications, and experience.	
Details and evidence of the labs competences • Collection and processing of samples for shipment to centralized testing facilities. • Bedside/point-of-contact testing and details of staff training • Screening and safety testing of clinical samples during the trial Specialized endpoint testing, i.e virology, immunology, cytokine analysis • Name of the organization • Department • Name of the contact person • Address • Telephone number • Fax number • E-mail	
Section 7: Information on the IP(s)	
Indicate if the information refers to the IP being tested or to the IMP used as a comparator, repeat as necessary.	
Status of the IP	
Does the IP for the trial have a registration elsewhere?	

If yes, provide the trade name, name of the marketing authorization holder and the country that granted registration	
For the purpose of this trial, is the IMP modified in relation to its registration?	
IPD submitted: • Full IPD • Summary of product characteristics (SmPC)	
Has this IP been previously authorized in a clinical trial conducted by any sponsor? If so, provide the authority's name, date and approval number, trial title, protocol number, [national] principal investigator, and date of the final report.	
Description of the IP	
Product name if applicable	
Pharmaceutical form	
Pediatric formulation? Y/N	
Maximum duration of treatment of a patient/participant according to the protocol	
Dose allowed: First dose for first-in-human trials, specify per day or total dose; units and route of administration. Maximum dose allowed, specify per day or total dose; units and route of administration.	
Estimated quantity of IP required for the trial	

(including overage) Route of administration	
Name of each active substance (INN or proposed INN if available)	
Strength (specify all strengths to be used): • Concentration unit • Concentration type (exact number, range, more than, or up to) Concentration (number)	
Type of IP	
Does the IMP contain an active substance of chemical origin or of biological/biotechnological origin?	
Is the IMP a: • Immunological product (vaccine, allergen, immune serum) Plasma derived product • Recombinant product • Radiopharmaceutical product • Herbal product • Other, specify	
Section 8: Medical condition or disease under investigation	
Medical condition/disease to be investigated; summarize the local epidemiology	
Therapeutic area	
Section 9:Objective of the trial	
Main objective: Secondary objectives:	

Section 9:Inclusion and exclusion criteria (list the most important)	
Inclusion criteria	
Exclusion criteria	
Section 10: End point(S):	
Primary End Point (repeat as necessary) Timepoint(s) of evaluation of this endpoint	
Secondary End Point (repeat as necessary) Timepoint(s) of evaluation of this endpoint	
Section 11: Scope of the trial	
Diagnosis	
Prophylaxis	
Therapy	
Safety	
Efficacy	
Pharmacokinetic	
Pharmacodynamic	
Bioequivalence	
Other, explain	
Section 12: Trial type	
Human pharmacology (Phase I) First-in-humans	

Bioequivalence Other, specify	
Therapeutic exploratory (Phase II)	
Therapeutic confirmatory (Phase III	
Therapeutic use (Phase IV)	
Section 13: Trial duration and recruitment	
Total duration of the study including follow-up	
Envisioned number of participants nationally	
Envisioned number of participants per site	
Section 14: Design of the trial	
Controlled yes □ no □ If yes, specify: Randomizedyes□ no □ Open: yes □ no □ Single blind: yes □ no □ Double blind: yes □ no □ Parallel group: yes □ no □ Cross over: yes □ no □ Other: yes □ no □ If yes to other specify: If controlled, specify the comparator: Other medicinal product(s) yes□ no □	

Placebo yes □ no □ Other yes □ no □ If yes to other, specify: Number of treatment arms in the trial	
Section 15: Definition of the end of trial:	
If it is the last visit of the last participant, please enter "LVLS". If it is not LVLS provide the definition:	
Initial estimate of the duration of the trial (years ,months and days):	
Section 16: Population of trial participants, Justify for inclussion of voulnerable participants if any	
Age range	
Less than 18 years yes □ no □ If yes specify the estimated number of participantsplanned in each age range for the whole trial: Approx. no. of patients 30. In Utero yes □ no □ ( ) Preterm Newborn Infants (up to gestational age < 37 weeks) yes□ no □ ( ) Newborns (0-27 days) yes□ no □ () Infants and toddlers (28 days - 23 months) yes □ no□( ) Children (2-11 years) yes □ no □ ( ) Adolescents (12-17 years) yes□ no □ ( )	

Adults (18-64 years) yes □ no □ ( ) Elderly (>= 65 years) yes□ no □ ( )	
Section 17: Gender	
Female□	
Male□	
Section 18:Group of trial participants	
Healthy volunteers yes □ no □ Patients yes □ no □ Specific vulnerable populations yes □ no □ Women of childbearing potential not using contraception.yes□ no □ Women of childbearing potential using contraception.yes□ no □ Pregnant women yes□ no □ Nursing women yes□ no □ Emergency situation yes □ no □ participantsincapable of givingconsent personally yes □ no □ If yes, specify Others: yes □ no □ If yes specify	

2.3. Form to **be filled by the Ethiopian Food and Drug Authority**

Date of receiving the request:	Date of request for additional information:
Date of request for information to make it valid:	Date of receipt of additional / amended information:
Date of valid application:	Grounds for non-acceptance/ negative opinion: □ Give date:
Date of start of procedure:	Authorization/ positive opinion: □ Give date:
Competent authority registration number: Ethics Committee registration number:	Withdrawal of application □ Give date:

Annex 3, The contents of any clinical trial protocols shall contain the following topics

1. General information
2. Background information

2.1 Preclinical studies
2.2 Clinical studies
2.3 Use of control group, placebo (if applicable)
2.4 procedure for emergency unbinding
2.5 Other concomitant therapy
2.6 Definition and the detail of the end of trial
2.7 Disclosure of financial conflicts of interest by the investigators

3. Trial objectives and purpose

3.1 Description of study risks and benefits

4. Trial design

5. Selection and withdrawal of participants
5.1 Inclusion criteria
5.2 Exclusion criteria
5.3 Description of recruitment and procedures
5.4 Procedures for discontinuation
5.5 Payment for participants
6. Treatment of participants
7. Assessment of Efficacy
8. Assessment of safety
8.1 Pharmacovigilance
9. Statistics
10. Direct access to source Data/Documents
11. Quality control and Quality assurance
12. Ethics
12.1 Informed consent
12.2 Assent (if applicable)
13. Data handling and Record Keeping
13.1 Confidentiality and Privacy
14. Financing and Insurance
15. Publication Policy
16. Supplements

Annex 4. Application for amendment of a clinical trial conducted in Ethiopia.

Title of clinical trial	
Date of application	
Cover letter attached	□Yes □No
1. APPLICANT	
Name	
Address	
Telephone	
Email	

Role in the clinical trial	
2. TRIAL PARTICULARS (original application)	
Trial Authorization Number	
Date of Authorization of original protocol	
Principal Investigator(s)	
Number of local sites approved for this trial	
Number of participants approved for this trial	
Name of the sponsor	
3. AMENDMENT PARTICULARS	
Does the applicant wish to increase the number of participantsparticipating in this trial?	□Yes □No
Does the applicant wish to change the dose / regimen of the study drug?	□Yes □No
Does this amendment request require a new consent form to be signed by the participant?	□Yes □No
If “Yes” please submit new patient information sheet together with this application	□Yes □No
Protocol Amendment Number	

Version Number and Date of Protocol Amendment (for each document submitted)	
General reason for the proposed Amendment: [List all of the issues included in the amendment, provide the rationale for each amendment and clearly highlight changes to the original protocol]	
If other documents are affected by the proposed change, please specify	
If the trial is multi center, will this Amendment apply to all approved sites	□Yes □No
If NO: Specify the site(s) for which the amendment will apply	
Is this amendment minor or major?	□Minor □Major
If minor, specify and list the reasons/ criteria	
If major, specify and list the reasons/ criteria	
4. ETHICS COMMITTEE APPROVAL	

Have the independent Ethics Committee(s) responsible for each center to which this amendment applies been notified?	
Name the responsible independent Ethics Committee(s)	
Date of application to independent Ethics Committee	
Date of approval by independent Ethics Committee	

I/We, the undersigned, confirm the above-mentioned information under the conditions as stated in this application are provided correctly. (The person(s) undertaking legal responsibility to sign this form).

Applicant Name_____

(Local contact) _____ Date_____

Annex 5 :SeriousAdverse Event reporting form

PROTOCOL AND EVENT TYPE	
Study title	
Protocol No.	
EFDA Ref No	
Date of this report	
Seriousness of adverse event	Death

	Life-threatening Initial or prolonged hospitalization Disability Congenital Anomaly Required intervention to prevent permanent impairment. Other medically important condition
Severity of the event	Mild Sever moderate Life-threatening Fatal
Was this event expected in terms of its severity?	Yes □ No □
Was this event expected in terms of its specificity?	Yes □ No □
Relationship of event to gene transfer product	Unrelated □Unlikely □Possible□ Probable □Definite □
Attribution of AE	Concomitant medication Product Intervention Underlying disease Route of administration Other suspected cause(describe)
DEMOGRAPHICS	

PI Name	
Name of clinical Trial site/Organization	
PI Telephone No	
PI E-mail address	
Reporter Name	
Reporter Telephone No	
Reporter E-mail Address	
Research Participant's Identification No.	
Research Participant's gender	
Research Participant's date of birth	
Research Participant's date of death(if any)	
Research Participant's weight in Kg	
Research Participant's height in cm	
Which arm/cohort/treatment group was the participant assigned to?	
Was the participant dosed?	Yes □ No □ Information not available□
What study product was received?	Investigational product □ Placebo□ Comparator product □
Were there any protocol deviations/ violations/exceptions for this participant?	Yes □ No □if yes, indicate in detail. ---------- ---------- ---------- ----------

	---------- ---------- ---------- ---------.
DETAILED ADVERSE EVENT INFORMATION	
Adverse event date	
Description of events	
Relevant tests(eg.X-rays) and results	
Treatment (s) of Adverse events(include medications used to treat this event)	
Name of concomitant medications(Do not include medications used to treat this event)	
Pre-existing conditions/ relevant clinical history(if this is an oncology trial, please designate primary disease, e.g.,Ovarian cancer)	
Date(s) of treatment(s) of the adverse event	
Was autopsy performed?(if applicable)	Yes □ No □
Date of Autopsy (if yes for the above question)	
Outcome of event	Recovered/Resolved. Recovering/Resolving Not recovered/not resolved Recovered/resolved with sequelae.

	Fatal Unknown
Documentation accompanying the report (e.g., H & P, Progress notes, discharge summary, lab or autopsy reports, other, etc)	
PRODUCT AND DOSING INFORMATION	
Name of investigational product	
Generic name	
Batch/Lot Number	
Manufactured date	
Expiry date	
Name and address of the manufacturing site	
Route of administration	
Site of administration	
Did the participant receive the dose specified in the protocol?	
If not the above what dose was given?	
Date of the first exposure of the product	
Total dose received prior to the event	
Total dose quantity administered to the participant to date	
Unit of measure of a single dose	
Dose quantity in a single administration	

If course used, how many were given prior to this event?	
How many doses on the last course were given?	
Was the administration of this product stopped because of this adverse event?	
Name of other treatment (s) (medications, radiation, surgery) received by research participant as required by the protocol	

Annex 6. Clinical trial summary of non-serious adverse event reporting form

Reporting Date:……

Clinical Trial:……

Clinical Trial site:……

Principal Investigators…… Signature……

Date……

S. No	Participant ID	Age	Sex	Treatment type*	Date of AE	Description of AE	Severity grading **	Causality results ***	Outcome#	Measures taken.	Remark
1											
2											
3											
4											

5											

**Investigational product or placebo or comparator product*

***Severity grading: Grade 1= mild, Grade 2=moderate, Grade 3= Severe and Grade 4= Life treating*

****Causality results can be certain, Probable/likely, possible, unlikely, conditional, unclassified etc.*

 # Outcome in the form of Fatal, Not resolved, Resolved, Resolved with sequelae, Resolving and Unknown

Annex 7: GMP certificate

Certificate of GMP Complianc

On the basis of the inspection carried out on -------- we certify that the site indicated on this certificate complies with GMP for the dosage forms, categories and activities listed in Table 1.

1. Name of the manufacturer: ----------
2. Address of inspected the site: ----------
3. Manufacturer's license number: **……..**

Table 1. List of Pharmaceutical Products, Dosage forms, Categories and Activities

S.No.	***Pharmaceutical products***	**Dosage forms**	**Category(ies)**	**Activity(ies)**
1	**Sterile**			
	1.1 Aseptically prepared			
	1.2 Terminally sterilized			
	1.3 Testing or batch release only			
	Non-Sterile			
2	2.1 Non Sterile products			
	2.2 Testing and batch release only			
3	Biological medicinal products (specify product types under the relevant sections e.g. allergens, antibodies, Vaccines, viral vaccines, rDNA etc.)			
	3.1 Blood products			

	3.2 Immunological products			
	3.3 Cell therapy products			
	3.4 Gene therapy products			
	3.5 Biotechnology products			
	3.6 Human or animal extracted products			
	3.7 testing and batch release only			

1) *The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.*
2) *This certificate remains valid for* ***……..*** *starting from date of inspection. It becomes in valid if the activities and/or categories certified here with are changed or if the site is no longer considered to be in compliance with GMP.*
3) *Address of certifying authority****:***
4) *Signature: Stamp and date:*

Explanatory notes

1) *This certificate certifies the status of the site listed on the certificate.*
2) *The certification number should be traceable within the regulatory authority issuing the certificate.*
3) *Where the regulatory authority issues a license for the site this number should be specified*

Annex 8: Requirements for clinical trial IP authorization applications

1) Specify in the application the types of medicinal products (include blood products, immunological products, cell therapy products, gene therapy products, biotechnology products, human or animal extracted products, homeopathic products, radiopharmaceutical products and products containing chemical active ingredients) and pharmaceutical forms to be manufactured or imported;
2) Specify in the application the relevant manufacture or import operations;
3) Specify in the application, where relevant as in the case of viral or non-conventional agents' inactivation, the manufacturing process;
4) Specify in the application the place where the products are to be manufactured or have at his disposal, for their manufacture or importation, suitable and sufficient premises, technical equipment and control facilities complying with the requirements of the manufacture, control and storage of the products have permanently and continuously at his disposal the services of at least one qualified person;

Annex 9: Format for contents of non-routine clinical trial applications

S.No	Baisc Information	
1.	Titile of the Study	
2.	Sponsor of the trial	
3.	Principal Investigators	
4.	Site of Clinical Trial	
Indication		
5.	Disease or condition going to be studied	
6.	Existing Therepay/Tretment for the condition if any	
7.	The Conditioon(s) for non Routine Procedure	
8.	Detail Explanation on proposed areas to be exempted as non-routine procedure	
Investigational Products		
9.	Name of product	
10.	Proposed Therapeutic Indication	
11.	Detail Justification/analysis of Risk and Benfit in relation to the proposed condition and available treatments if any for non-routine CT authorization procedure	
12.	Detail explanation of on areas of exemption in relation to investigational product	
Other Relevant Adminstrative Documents		
	Sponor declaration that the trial is candidate for non- routine procedures	

13.	Document proposed for exemption if any for non-routine procedure	
For authority use only		
14.	Screened by	Comment/Statement:
15.	Approved By Name	Comment/Stament:

Signature of Sponsor: Signature of PI:
Date: Date:

Annex 10. Content of notification of premature discontinuation or termination of a clinical trial

This notification shall include:

1) Detailed reason(s) for this action;
2) Description of the impact on the proposed or ongoing trials conducted in the country.
3) Confirmation that all qualified investigators have been notified of the discontinuation and the reasons for the discontinuance and have been advised in writing of any potential risks to the health of clinical trial participantsor other persons;
4) Confirmation that the sale or importation of the drug to the discontinued sites has been stopped; and
5) Confirmation that reasonable measures will be taken to ensure the return of all unused quantities.
6) What is the fate of the safety of the participants that were involved in the clinical trial
7) Plan for data handling from the interrupted CT, final report