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ประกาศกองยา

เรื่อง รายละเอียดข้อกำหนดเกี่ยวกับการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิก

ด้วยกองยาได้กำหนดรายละเอียดการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิกเพื่อเป็นวิธีปฏิบัติในการจัดเตรียมเอกสารให้ครบถ้วนถูกต้องและเป็นวิธีในการปฏิบัติตามเงื่อนไขในการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิก ตามประกาศสำนักงานคณะกรรมการอาหารและยา เรื่อง ข้อกำหนดเกี่ยวกับการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิก ลงวันที่ ๑๗ กันยายน ๒๕๖๑ ข้อ ๒ ข้อ ๓ (๔) (๕) และ (๖) ข้อ ๔ (๑) และ (๒)

เพื่อเป็นการส่งเสริมการปฏิบัติตามมาตรฐานสากลที่เกี่ยวข้องกับยาวิจัยทางคลินิกและเพื่อเป็นการอำนวยความสะดวกด้วยระบบอิเล็กทรอนิกส์ กองยาเห็นควรปรับปรุงข้อกำหนดเกี่ยวกับเกี่ยวกับการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิก กองยาจึงออกประกาศ ดังต่อไปนี้

ข้อที่ ๑. ให้ยกเลิกประกาศสำนักยา เรื่อง รายละเอียดข้อกำหนดเกี่ยวกับการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิก ลงวันที่ ๕ กุมภาพันธ์ ๒๕๖๔

ข้อที่ ๒. ให้ยื่นคำขอพร้อมเอกสารประกอบผ่านช่องทางอิเล็กทรอนิกส์ของกองยา

ข้อที่ ๓. รายละเอียดเกี่ยวกับคำขอ เอกสารประกอบ การยื่นคำขอ และการดำเนินการหลังจากได้รับอนุญาตนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัย ให้เป็นไปตามข้อกำหนดในรายละเอียดแนบท้ายประกาศฉบับนี้

ทั้งนี้ ให้ประกาศฉบับนี้มีผลบังคับใช้ตั้งแต่บัดนี้เป็นต้นไป

ประกาศ ณ วันที่ ๒๗ สิงหาคม พ.ศ. ๒๕๖๖

(นางสาววรสุดา ยูงทอง)

ผู้อำนวยการกองยา

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Attachment to the Announcement of the

Division of Drugs on the details of requirements relating to importing or ordering drugs into the Kingdom

for clinical research, dated August 7, 2023

Summary of changes in this issue

a. Added clarifications on some documents, i.e. Form Nor Yor Mor. 1 and research project summary (Thai language) that have been changed to electronic data filling system b. Research project summary (language Thai) Added clause 21, category of the main investigative drug of the project, for use in classifying the request and revised the original clause 25 by separating into 2 clauses, clauses 25 and 26, which are usually in different documents for reference. accurately and clearly

C. Add power of attorney instructions for submitting applications electronically D. In case of paper submissions Changed from using MS Excel template files to MS Word files E. Improved drug labeling requirements. In the case of drug preparation for drug administration at the research site, new labeling is required, with strict compliance requirements. check it yourself and along with inspection from the authority But the label in this case is not required to be submitted to the pharmaceutical division.

f. Revise topics on requesting permission to make changes before proceeding and notifying them. The types of changes are classified according to the appendix. "Guidelines for action when there is a change" and revised related procedures. g. Improved document self-examination form

new drug groups and promote drug research

Medicine Division

Food and Drug Administration

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specification details

Regarding bringing or ordering drugs into the Kingdom

For Clinical Research (Revised 7 Aug. 2023)

1. Requirements for submission of applications and supporting documents for permission to import or order drugs into kingdom for research

1.1. Requirements on Eligible Applicants

1.1.1. An application for permission to import or order drugs into the Kingdom for use in the same research project, one **person must Apply for permission from only one agency.** By "being a single research project" means being an outline.

the same research (Considering from the research project code established by the research project initiator or the name of the research project the same)

1.1.2 Eligible applicants refer to Notification of the Ministry of Public Health No. 14 (B.E. 2532) **(Appendix** 1). namely

(1) A licensee to import or import drugs into the Kingdom (2) Ministry or Department in the duty of disease prevention or treatment (3) Thai Red Cross Society or

(4) Government Pharmaceutical Organization **In the case of the applicant not operated manually Attach a Power of Attorney for every request** (see details in clause **1.16)**

1.2. Requirements on Nor.Mor.1 form

1.2.1. For submitting via the electronic system, you will fill in the information in the system. to create a request form Nov. 1 automatically through the system

1.2.2. For submission of paper forms (Only in case of necessity, the officer deems that it cannot be submitted through electronic system only) must submit Form Nor Yor Mor 1 which is correct according to the notification of the Ministry of Public Health on rules, procedures and conditions for importing or ordering drugs into the Kingdom. without having to ask for a recipe registration Drug No. 2 (B.E. 2552) dated April 27, 2552, 2 copies, **see Appendix 2.**

1.2.3. Complete and correct information in the request form by typing.

1.2.4. The name of the research project in Thai was the same as the document approved by the ethics committee, except for the case where the relevant research ethics committee was awaiting approval. The project name should be given correctly. matched in documents of all relevant research sites. and match that specified in the research project summary (Thai language) **(Appendix** 3)

1.2.5. Must be signed with the original signature of the authorized person only. both in the original and in the copy

1.2.6. The person who signs the request is

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(1) In the case of "a licensee to import or order drugs into the Kingdom", the signatory must be the operator of the business. As specified in the license to import or order modern drugs into the kingdom. (2) In the case of "Ministry, Department in the duty of prevention and treatment, Thai Red Cross Society or Pharmaceutical Organization", the signatory must be Chief executives or persons assigned to perform official duties on their behalf in relevant duties with importing or ordering drugs into the Kingdom. In this regard, a copy of the order of the Department in the case of performing official duties on behalf of the Director-General of the Department or a copy of the university's order In the case of performing official duties for the Rector university

1.3. Research Project Summary Requirements (in Thai) are in accordance with the form in **Appendix 3,** completed and endorsed, with some additional clarifications as follows:

1.3.1. Finances" provide evidence of financial support, which may be included in the protocol document. or information sheet for volunteers or other documents which need to be additionally attached

1.3.2. Clause 26 "Evidence of insurance or compensation in the event of an accident, illness, injury, disability or death of a volunteer. as a result of clinical research", provide evidence showing Insurance or indemnification in the event of a volunteer's illness, injury, disability or death. as a result of clinical research It may be a document issued by an insurance company. or agreement documents specify Responsible Person and Responsibility Including payment of various compensation 1.3.3. In case of filing via electronic system, it will be filled in electronic information to generate Research Project Information **1.4. Requirements for Certification of Compliance with Terms and Conditions Regarding the Importation or Prescribing of Drugs in the Kingdom for clinical research for the applicant** Certificate of Compliance with Terms and Conditions Regarding Importing or Ordering Drugs into the Kingdom for clinical research For the applicant,

Nor.Yor.Mor.1, as detailed in **Appendix 4 ,** with the signature of The same person who signed the Nor Yor. Mor. 1 form . **in the Kingdom for clinical research for the principal investigator** Certificate of Compliance with Terms and Conditions Regarding Importing or Ordering Drugs into the Kingdom for clinical research For the principal investigator stationed at each research site in connection with the authorization. This time, as detailed in **Appendix 5 ,** all institutional principal investigators are required to sign one document each.

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1.6. Requirements on the labeling of all drug sizes

1.6.1. Submit a label or a picture of a label for every container and every size. with a pattern like a label

actually use

1.6.2. Use Thai language, except for drug names/codes. and information about research project sponsors use Thai language or can english and in the case of drugs administered by healthcare professionals Thai or English can be used. 1.6.3.

In general cases, labels on both the primary and secondary packaging must contain at least the following information: (1)

drug name/code, dosage strength, pharmaceutical form, channel give medication unit quantity In the case of a blindfolded research The label must be labeled **"placebo or [drug name/drug code].**

+ [strength size]"

(2) protocol code or protocol name; (3) batch and/or

code number to identify ingredients and packaging procedures; (4) subject number or

treatment number. and appointment number (5) Medications may be referred to a document specifically

created to explain to subjects (eg, dosing records) or personnel handling the drug products. to communicate that volunteers or personnel who are (6) The name, address and telephone number of the research sponsor or contract research organization or investigator (main point of contact for product

information; clinical research and Disclosure, Concealment, Emergency Treatment), unless the subject has been provided with an identification card showing these information and has been instructed to keep this document in their possession at all times. only" or other words with the same meaning in Thai. (8) Storage conditions of the drug. (9) Period of use. (Use by date, expiration date, or re-test date as appropriate)

in month/year format and in a manner that avoids ambiguity (10) The statement "Keep out of reach of children" or

other words that have the same

meaning in Thai except

Volunteers did not take the medicine home.

1.6.4. **The case of the primary packaging is always in conjunction with the secondary packaging. (when the packaging label** The **label of** the primary package must contain at least the following information:

(1) drug name/drug code, size, strength, pharmaceutical form Dosing route (except oral solid dosage form) Unit dose In the case of a closed-up research, the label must contain the statement **"placebo drug or [drug name/drug code] + [strength]" (2)** protocol code or protocol name (3) batch and/or number. Code, to identify the

ingredients and the packaging procedure. (4)

Volunteer or Treatment Number. and appointment number (if applicable) (5) Name of

research sponsor or contract research organization or investigator.

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1.6.5. **In the case of primary packaging in blister form or small units with an area not exceeding 3 square inches (when the outer packaging label contains the details in Section 1.5.3 and the primary packaging is always in conjunction with the secondary packaging).** The label of the primary packaging shall contain at least the following information:

(1) Dosing channel (The route of administration may not be specified for solid dosage forms administered orally.) and in the case of open research, specify the name of the drug/drug code, and Strength

(2) protocol code or protocol name; (3) batch and/or code number to identify the ingredients and packaging procedure; (4) subject number or treatment number. and appointment number (if applicable) (5) Name of trial sponsor or contracting research organization or investigator 1.6.6. Drug

labeling must be performed in accordance with standards in licensed pharmaceutical manufacturing facilities. and in accordance with the announcement of the Ministry of Public Health on the determination of details on criteria and Methods for producing modern drugs and amending the criteria and methods for producing traditional drugs according to the Drug Law B.E. 7. **In the case of drug preparation for drug administration at the research site, the label must be re-labeled on the packaging to be used for drug administration,** such as preparation or mixing of injectable drugs. preparation for immediate oral dispensing, etc. The applicant shall ensure that the primary investigator or designee (1) produces a label containing information that is appropriate and accurate to the study objectives; (2) provides Manual of Standard Operating Procedures or how it is Standards for drug preparation and drug labeling are in line with current criteria and methods for the production of drugs.

(3) Operate according to the manual by pharmacists or other health professionals of approved research sites. proper training

(4) There is evidence to record the practice. are audited by at least a second party under the supervision Strictly control labeling

(5) Keep relevant evidence and records of documents to support auditing by authorized persons. power or medicine

The applicant is not required to submit a label in this case with the request but must ensure that the primary investigator or recipient assign actions in accordance with these requirements and always ready to be inspected or monitored for research

1.6.8. If necessary Applicants may request the Drug Division to consider waiving the above-mentioned labeling requirements only in the following cases: can be changed in a timely manner when applying for permission (passed the request and accepted the system) times first within 30 April 2021

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(2) Information on the label that may refer to other documents, such as the method of administration of the drug, referring to the medication record, etc. by Attach reference documents with explanations.

(3) Additional labeling after drug importation into Thailand in order to comply with research drug labeling requirements: 1) Label or image of the label that resembles the actual label used; Labeled as a licensed premises for the manufacture of legitimate drugs or, if necessary, may request a waiver Instead, labeling is carried out in places where it can be controlled according to the conditions. which must be performed by Appropriately trained pharmacists or other site health professionals or research supervisors establish procedures. practice record There are inspections by a second party, labeling is strictly controlled. and the operation must be consistent with the rules and procedures for Modern drug **manufacturers Drug labeling requirements are case-specific (Appendix 6) .** In all cases, the rights, safety and well-being of the subjects must be taken into account. as well as reliable clinical research results.

1.6.10. For drug labels that have been submitted to the Drug Division and have been permitted to import or order drugs into the kingdom. for research The applicant may refer to the original document if there is no change from the original.

1.6.11. In case of requesting to change information about the period of medication use Add a label indicating the new date and use the original production model. Submit a label or label image with the same format as the actual label. which may overlap the original date but must not close Superimposed on the original production model for quality control reasons, this must be done in a licensed facility. Produce the right medicine or, if there is a necessity may request a waiver of labeling operations in places where it can be controlled according to the conditions instead This must be labeled by a pharmacist or other health professional. of a research site or an appropriately trained research supervisor. Prepare operational procedures practice record It is verified by a second person. There is a strict control over labeling and the operation must be in accordance with the criteria and methods for the production of modern drugs (submitting a **waiver form). Drug labeling requirements are case-specific (Appendix 6)).**

1.6.12. Recommendations for drugs used in the protocol for use for an established indication. Registered in Thailand as a drug procured from the market in Thailand and there is no reason to pass production process or packaging process The following text should be added to the original container, but must

Do not overlap the original label.

(1) Name of research sponsor or contract research organization or researcher

(2) Research project code

(3) Text “Clinical use only” or other words with the same meaning in Thai

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1.7. Requirements for accompanying documents (for prescription drugs)

1.7.1. In the event that the applicant submits evidence “Documents for quality control and drug production” with reference to the Registration of drug formulations in Thailand Use the drug leaflet approved by the Office of the FDA. food and medicine

1.7.2. In the event that the applicant submits evidence “Documents for quality control and drug production” with reference to the Registration of drug formulations abroad Use the accompanying document of that country. If in a foreign language not english translate into Thai or English and certify that other language texts match Thai/English 1.7.3. See “Relationship Tables

between Drug Quality Control and Manufacturing (CMC) Documents, Drug Information Documents (i.e. Prescription Documents (PI) and Investigator (IB) and Producer Documents)” in Topic “Requirements for Quality Control Documentation and Drug Production” **1.8. Requirements for**

Investigator Documentation. (Investigator's Brochure) (for drugs that have not yet been published

1.8.1 . The

Investigator's Handbook is in accordance with the current ICH Good Clinical Practice Guideline. 1.8.2. The

Investigator's Handbook should be reviewed at least once a year and should be revised as needed. necessary and may be revised more frequently as the drug development phase and new information increases

1.8.3. There is evidence that the investigator's handbook has been presented to the ethics committee, except for pending approval by the relevant research ethics committee. 1.8.4. Contains the following information, each section should be

referenced as appropriate.

(1) Table of

contents (2)

Summary (3) Introduction

(4) Physical, chemical and pharmaceutical properties including formulation (5)

Animal studies

a. pharmacology b.

pharmacokinetics and transformation in laboratory animals

C. Toxicology

(6) Clinical study results a. Pharmacokinetics and

product conversion process in human research

b. Safety and effectiveness

c. Marketing experience (7) Summary of information and

recommendations for the researcher.

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1.9. Patient Information Sheet Requirements (Thai language) 1.9.1. This section covers the Patient Information Sheet and Consent Letter. 1.9.2. Approval from the Ethics Review Board. in person, except in the case of waiting Approval from the relevant research ethics review committees. submit the version under consideration 1.9.3. Volunteer guidance documents are in accordance with the original edition of the ICH Good Clinical Practice Guideline. Presently 1.9.4. There are languages suitable for volunteers, for example, Thai volunteers submit the Thai version, foreign volunteers translate into Thai, and certify that the text in other languages corresponds to the Thai version. 1.9.5. providing information and explanations during the consent process and in the consent document as well as other documents to be provided to volunteers It must include the following details: (1) indicating that the project is a research, (2) the purpose of the research, (3) the treatment provided in the research and the likelihood that subjects will receive either of the following treatments. random selection method; (4) research method, including various methods. that has invaded (invasive) the body of volunteer (5) The subject's responsibilities; (6) The part of the experimental research project; (7) Potential risks or inconveniences to the subject. and in some cases old an infant or fetus or infant who is breastfed (8) Reasonably expected benefits Where the trial does not produce clinical benefit to the subject, the subject should also be informed (9). that volunteers may receive including benefits and the significant risks of those alternatives; (10) the compensation and/ or treatment that the subject will receive; In case of danger resulting from research (11) Compensation (if any) determined on a case-by-case basis to the subjects participating in the research; (12) Expenses (if any) for the subjects participating in the research; Subjects' participation in the research is voluntary, and subjects may refuse to participate or withdraw from the research at any time. without fault or Loss of benefits that volunteers should receive. (14) Statements stating that the Food and Drug Administration Research regulators, research investigators, IRB/IEC and regulatory bodies will be authorized to Directly check the original medical records of the volunteers to verify the correctness of the procedure.

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clinical research and/or other information without violating the subject's right to confidentiality beyond To the extent permitted by laws and regulations, by signing the consent form. Volunteers or their legal representatives allow individuals to The above has the right to examine the medical Direct Volunteer Original Records

(15) Include a statement stating that the records identifying the subject's personal information will be kept confidential and that such information will not be disclosed to the public beyond the scope of the law. and/or regulations The law permits. in the publication of research results Volunteer personal information will remain confidential.

(16) There is a statement stating that the volunteer or legal representative will be notified of new information in due time This may affect the subjects' willingness to continue participating in the research.

(17) Persons to contact for further information about the trial and subjects' rights, and persons to be notified in the event of trial-related

harm; (18) Circumstances and/or reasons for subject's withdrawal from

(19) Estimated duration of subjects participating

in the trial (20) Estimated number of subjects participating in the entire project and the number of Volunteers from each institution in Thailand

1.10. Complete Study Protocol Detail Requirements

(Thai or English language)

1.10.1. Approval from the Human Research Ethics Committee is granted, except in the case of pending approval from the relevant Research Ethics Committee. Submit the latest available version.

1.10.2. The protocol is in accordance with the current ICH Good Clinical Practice Guideline 1.10.3. It must contain detailed information.

(1) General Information (2)
Background Information (3) Trial Objectives
and Purpose) (4) Trial Design (5) Selection and Withdrawal
of

Subjects)

(6) Treatment of Subjects (7)
Assessment of Efficacy (8) Assessment
of Safety (9) Statistics

(10) Direct Access to Source
Data/Documents)

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(11) Quality control and quality assurance of research (Quality Control and Quality Assurance)

Quality Assurance)

(12)Description of ethical considerations relating to research

to the trial)

(13) Data handling and record keeping

Keeping)

(14)Financing and Insurance (if not specified

In this document, separate agreements may be attached.)

(15) Publication Policy

(16) more details (Supplements)

1.11. Requirements for quality control documentation and pharmaceutical production

It consists of 2 parts of the document:

1.11.1. Evidence summary form for quality control documents and pharmaceutical production classified by drug according to the details in **Appendix 7.** The identification of the manufacturer of each drug confirms that the drug being introduced into the study will have The manufacturer actually and must match those specified in the excel file for the logistic system (see additional requirements in topic 1.16)

1.11.2. Evidence of quality control and pharmaceutical production documentation Provide evidence of 1 of the following 4 items.

(1) NCE (New Chemical Entity) drug quality information

Details according to the topic specified in Evidence of drug quality NCE (New Chemical Entity)

Appendix 8 for the different phases of research. As specified in the table, must be attached **a certification letter Good Manufacturing Practice of pharmaceutical manufacturers issued by pharmaceutical regulators** to Assembling the heading " Attestation that the dosage form was manufactured under Good Manufacturing Practices (GMP) conditions" every time.

(2) Refer to the registration of drug formulas in Thailand. by informing the registration certificate number along with a copy of the document. In this case, it can be used as a reference. Only when the drug to be used for research is from the same manufacturer. with the manufacturer listed in the drug formula registration in Thailand

(3) Certificate of Pharmaceutical Product (CPP) (see **Appendix** 9)/ Certificate of

Free Sale (CFS) **(see Appendix 10)** together with Good Manufacturing Practice Certificate.

In this case, it can be used as a reference. Only if the drug to be brought into the study is from the same manufacturer as the manufacturer identified with the increase.

Drug formula registration in that foreign country and CPP/ CFS indicates that the drug is registered for sale in the market of that country too

(4) Other evidence showing registration from drug regulatory authorities, such as information

Print from the website of the Drug Regulatory Authority (NRA) of the country in which the medicine is registered. Registration number specified in the drug document or drug label that has been registered, etc., if unable to find the document

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Show the manufacturers involved in the registration, attach an additional Certificate of Analysis (COA).

Yes, in this case it can be used as a reference. Only if the drug to be used for research comes from the same manufacturer as the specified manufacturer.

with the registration of drug formulas in that foreign country

1.11.3. Table showing the relationship between quality control and pharmaceutical manufacturing (CMC) documentation.

Drug Information (i.e. Prescription Document (PI) and Investigator (IB) Documentation) and drug manufacturer

at	Type of Evidence CMC Drug Data Sheet	Drug Manufacturer
1 NCE + GMP Certificate	IB	As stated in NCE
2 Register a drug formula in Thailand	Thai PI	as specified in the Pharmacopeia Register in Thailand
3 CPP/CFS	Country PI based on evidence	As specified in CPP/CFS
4 Foreign registration (NRA web page/ no. registered in the PI or label)	Country PI based on evidence	as specified on the webpage/ PI/ label (if The producer was not found in all 3 types of evidence. Applicant confirms manufacturer with COA)

1.12. Requirements for research approval documents from the research ethics committee in Persons (IRB/ IEC) recognized by the Food and Drug Administration

1.12.1. The applicant is responsible for obtaining approval to conduct research from the review committee.

Research ethics in people recognized by the Food and Drug Administration and have been approved before start research This is in accordance with the announcement of the Food and Drug Administration regarding criteria, methods, and conditions for acceptance of human research ethics committees considering clinical research projects.

about medicine

1.12.2. A copy of the research approval document from the Human Research Ethics Committee must be submitted.

that the Food and Drug Administration accepts the Thai version, however, the approval document must contain information at least the following

(1) name of the committee as accepted by the Food and Drug Administration

(2) name of the research project in Thai

(3) Researcher's name

(4) Names of all approved research sites.

(5) research project documents and related documents, along with specifying the version (Version) that the Board Consider the ethics of research in approved subjects. and/or expiration date

1.12.3. Cases awaiting consideration by the Research Ethics Committee Eligible person

Requests may be submitted to the Food and Drug Administration before the Ethics Review Board.

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Researchers in human subjects can approve or endorse research projects. The person who has the right to submit the request must comply with the conditions set forth

The Food and Drug Administration set

1.13. Requirements for documents approved by relevant technical committees.

Research on certain drugs may be subject to special oversight, for example, AIDS vaccines. For example, the AIDS Vaccine Trial Academic Sub-Committee, etc. Therefore, when submitting an application for permission, a copy of the document for approval or approval from the said committee must also be submitted. **1.14. Requirements for the document self-examination form**

Prepare documents and evidence according to **Document self-examination form for permission to bring or Order drugs into the Kingdom for research purposes** (Nor.Mor.1) (see **Appendix 11)** and check completeness.
of the document itself

1.15.Requirements on drug calculation documents

1.15.1. Show the calculation for the number of subjects at each research site reviewed by the Committee. Approval Research Ethics calculated according to the reference dosing as specified in the protocol. properly for use throughout the trial period. And as usual, the allowance for damage can be calculated at 20%, except for bioequivalence studies, allowing for repetition 1 more time, up to 2 times.

1.15.2. In case of clinical trials in which days, months or years of dosing are not defined
Of course, calculate no more than 4

years. 1.15.3. Once the research has been carried out. The number of licensed drugs is insufficient. If the medicine is damaged or the medicine has expired, you can apply for a new license for the missing amount. damaged or expired with reasons and Relevant Evidence Documents

1.16. Provisions relating to Power of Attorney and Power of Attorney

1.16.1. The top management of the authorized entity may authorize a qualified person to process, submit the request, clarify, correct, receive documents regarding the request. The attorney should be knowledgeable . **Pharmacy or medical related field as well as having an understanding of the request for permission and related documents** 1.16.2.

clarify, amend documents requesting permission

1.16.3. stamp duty 30 baht

1.16.4. Copy of identification card of attorney and attorney. 1.16.5. One Power of Attorney is for 1 request only. 1.16.6.

Let's proceed through the group.

Developing the drug division system

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1.17.Template File Requirements In case of submitting a paper form

Where necessary, at the discretion of the staff A paper request may be submitted. but the applicant A template file must be filled in for importing data into the information system in order to be able to connect to drug import. and further supervision of clinical research. Please use the template file on the Medicine Division website or ask staff.

2. Amendments/submission of additional documents according to the assessment results

If the result of consideration from the appraisers allows the applicant to correct / clarify various issues to the applicant/grantee Authorized to correct/ clarify according to the evaluation results within the specified time by submitting a request for correction/ clarification **(Appendix 12)** together with relevant documents and evidence. for clinical research medicine Regulatory group before entering the market, Division of Drugs, in

case of submission via electronic system, proceed according to the system's procedures.

3. Submission of the results of consideration from the Human Research Ethics Review Committee and relevant documents and evidence in the case of submitting an application for importing or ordering drugs into the Kingdom for research prior to obtaining approval from the Human Research Ethics Review Committee

authorized person The results must be submitted for consideration by the Human Research Ethics Committee. The Food and Drug Administration accepts the drug within **15 days from the date of receipt of the consideration results. From the Human Research Ethics Committee accepted by the Food and Drug Administration. All are involved.** By using the letter submitting the consideration results from the Human Research Ethics Committee **(Appendix 13)** with the Thai version of the consideration results attached. and related documents in The research project has been revised according to the opinions of the Food and Drug Administration and the committee. Consider the ethics of research in human subjects and present the revised sections. Requests that already contain information electronically. Send documents according to the system's procedures.

4. Actions after permission to bring or order drugs for research After being

allowed to bring or order drugs for research As the case may be, the authorized person must take the following actions:

4.1.Reporting the progress of the research

The research progress report is required to be submitted annually between **1-31 October** of every year until the end of the research project using the research project progress report form **(Appendix 15)** and the submission letter **(Appendix 14)** From the authorized person to the Director of the Drug Division. Requests that already contain information electronically.

Send documents according to the system's procedures.

4.2. Actions upon change Various changes must be

considered according to the guidelines for action when there are changes **(Appendix 16)** by dividing changes into 3 groups: 1) Changes that must be notified.

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2) Changes that must be submitted before implementation, and 3) Changes that must be submitted before Apply for a new production permit **4.3.**

Procedures for obtaining permission for alterations that must be obtained before

proceeding When it is considered that the change or situation is in accordance with the guidelines specified above, proceed to submit a request for change by (1)

requesting for permission to change. Prepare documents and evidence according to **document check form by themselves for requesting to amend the items regarding permission according to Form Nor.Mor.1 / Por.Por.8 for human research studies (Appendix 17).**

(2) Submit a **request to amend the details regarding permission according to the form N.Y.M.1 / P.Y.8 for human research studies (Appendix 18)** 1 set (3) Attach documents that Relevant

by showing in the revised section and attaching 1 set of power of attorney (4). Please note that 1 request can only change 1 main issue, such as in the case of requesting to extend the life of medicine. (This is a change in quality and results in a new expiration date label) to be submitted in 1 request, etc.

(5) Requests that already contain information in an electronic system Send documents according to the system's procedures.

4.4.Procedures for noticeable changes Once it is determined that

the change or situation has met the guidelines outlined above, proceed to notify the Division of Medicine. Was handed in a letter explaining and referring to the license to bring or order drugs. kingdom for research ever received along with attaching relevant documents as shown in the revised section or what you want to notify As detailed in **Appendix 19.**

4.5. Termination or termination of the

research project A research project termination/termination summary notification form must be submitted. along with drug details Remaining to destroy or return and evidence for destroying or returning the drug As detailed in **Appendix 20,** within 60 days of the closure of the research project at the last research site in the country.

Thai

Requests that already contain information electronically. Send documents according to the system's procedures. **4.6. Reporting of adverse reactions from**

drugs used in research must be in accordance with the criteria and methods for reporting adverse reactions from drugs used in clinical research, as detailed in Appendix **21.**

4.3. Facilitating officials in inspecting research (Inspection)

The Food and Drug Administration has measures to monitor research that is permitted to be taken or ordered. Drugs enter the kingdom for research purposes. This may be done in the pre-research period. during the research or after the research is over or after termination of the research project

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Generally, a designated official will contact the licensee to make an appointment to know the inspection schedule. before and have an official notice of the schedule at least 7 days in advance, except in cases where the office The Food and Drug Administration has special orders to conduct research inspections immediately. This may be given in a short period of time or without prior notice.

Those who are allowed to bring or order drugs into the kingdom for research purposes will cooperate and facilitate. Convenience for inspectors As in the following example: -

Notify relevant parties, e.g. principal investigators and staff. Ethics Committee related research, etc.

- Assign a coordinator to be the representative to contact the inspector before the research inspection -

Send information to the inspector team in advance According to the list stated in the notification of the research inspection clinic

Prepare various equipment and locations: 1) As follows: -

Conference room for opening and closing meetings of research inspections. which will be used on the first day and day The last of the research surveillance, respectively.

2) A room for inspectors who will be able to examine various documents. during patrol

3) A computer that can be connected to the data recording/reporting system of volunteers in This research project, both the original data and the patient record in case of storage. electronic data as well as all electronic systems used in conduct research

4) Internet network system 5)

Locations used for each step of the research project for surveillance such as examination rooms, laboratories. Drug storage location, etc. - Prepare documents

as appropriate for the current research project status (refer to ICH GCP, Item 8, Essential documents for the conduct of a clinical trial [8. Essential documents for the conduct of a clinical trial]) and relevant licenses from the Food and Drug Administration are kept at the research sites listed above. - Prepare safe lunch and drinking water

in sufficient quantity and value

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Appendix 1

(copy)

Announcement of the Ministry of Public Health No. 14 (B.E. 2532) on the criteria, methods and conditions for importing or ordering drugs into the Kingdom. without having to register the recipe

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By virtue of Section 79 bis (4) of the Drug Act B.E. 2510 as amended by Drug Act (No. 5), B.E. 2530 Minister of Public Health With the approval of the Drug Committee, the announcement is issued as follows: Clause 1 In this announcement, “drug” means a modern drug. or traditional medicine “Drug production licensee” means a licensee to produce modern drugs or a licensee to produce traditional drugs. “License to import or order drugs into the kingdom” means a person licensed to import or order modern drugs. into the kingdom, or a licensee to bring or order traditional medicines into the kingdom. Article 2. Importing or ordering drugs into the kingdom that will be exempt from the need to apply for drug formula registration must be imported for research purposes. Analyze the exhibition or charitable donations

Article 3 Bringing or ordering drugs into the Kingdom for research or analysis must be in accordance with The requirements are as follows: (1) The importer must be a drug manufacturing licensee. A licensee to bring or order drugs into the Kingdom Ministries, bureaus, and departments in the role of disease prevention and treatment, Thai Red Cross Society, or the Government Pharmaceutical Organization.

(2) The importer must submit an application using Form Nor.Yor.Mor.1 or Nor.Yor.Mor.2 attached to this announcement. along with the evidence as specified in Form Nor.Yor.Mor.1 and Nor.Yor.M.2, as the case may be.

Clause 4 Importing or ordering drugs into the kingdom for exhibition purposes shall be in accordance with the following requirements: (1) The importer must be a licensee for production. A licensee to import or order drugs into the kingdom, ministries, bureaus, departments in the duty of prevention and treatment of diseases, the Thai Red Cross Society, the Government Pharmaceutical Organization. Associations or foundations that are juristic persons or trade representatives of foreign countries

(2) The importer must submit an application using Form Nor.Mor.3 annexed to this announcement. along with the evidence as specified in the form Nov. 3

(3) The importer must take or return all such drugs. along with sending a letter of introduction or delivery be returned to the Ministry of Public Health or given to the Ministry of Public Health within 1 month from the date of the performance The exhibition ends. Article 5 Bringing or ordering drugs into the Kingdom To donate for charity in accordance with the following requirements

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(1) The importer must be a licensee to produce drugs. A licensee to bring or order drugs into the Kingdom

Ministries, bureaus, departments in charge of disease prevention and treatment, Thai Red Cross Society, Government Pharmaceutical Organization Foreign Red Cross or

Associations or foundations that are juristic persons

(2) The importer must submit an application in accordance with Form Nor.Mor.4 annexed to this announcement. along with the evidence as specified in the form

Nov. 4

(3) Donations must be donated to ministries, bureaus, and departments in charge of disease prevention and treatment, the Red Cross Society.

Thai or private hospitals approved by the Ministry of Public Health

(4) The importer must submit evidence of acceptance of such drug donation to the Ministry of Public Health within

1 month from the date of import

Article 6 A licensee to produce drugs or a licensee to import or order drugs into the kingdom will request permission.

Modern drugs or traditional drugs can be imported for the purposes of clause 2 only modern drugs or traditional drugs that they

Licensed depending on the case

Clause 7 The application under this announcement shall be submitted at the Drug Control Division, the Food and Drug Administration.

Ministry of Public Health

Section 8 Permission: The grantor may express permission in the request for permission or may issue a permit. and will be allowed with

conditions or time or with both conditions and time conditions

Announced on 28 May 1989

(Signed) Chuan Leekpai

(Mr. Chuan Leekpai)

Minister of Public Health

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Appendix 2

Form Nor.Mor.1

Application for permission to bring or order drugs into the kingdom for research purposes

Receipt No.....

date.....

Signed.....Recipient

Type ÿ Modern medicine

ÿ Traditional medicine

1. I (Mr./Mrs./Miss) ----------

position ----------

On behalf of ÿ Ministry ---------- ÿ Ministry ---------- ÿ Department ----------

ÿ Thai Red Cross ÿ Government Pharmaceutical Organization

Society ÿ Licensee to produce ---------- license number ----------

drugs, name ÿ Licensee to take or order drugs at the place named ---------- license number ----------

located at ---------- Alley/Alley ---------- road ----------

Moo No. ---------- sub-district ---------- District/District ----------

province ---------- telephone ---------- fax ----------

Intend to request permission to import or order drugs into the Kingdom for research purposes.

2. Name of the research project

(English) ----------

(Thai language) (if any) ----------

---

3. Research project code (if any) ----------

4. Research site ----------

---

5. Drug name

(1) Drug name or drug code ---------- drug form ---------- quantity ---------- Details of every packing size ----------

(2) Drug name or drug code ---------- drug form ---------- quantity ---------- Details of every packing size ----------

(3) Drug name or drug code ---------- drug form ---------- quantity ---------- Details of every packing size ----------

(4) Drug name or drug code ---------- drug form ---------- quantity ---------- Details of every packing size ----------

(If there are more details Please attach additional documents with the same format. which has the number of.....pages)

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6. Enclosed evidence as follows:

(1) drug labels for every package size *(Thai or English)*

(2) Document accompanying the drug (For drugs that have been registered with the drug formula)

(3) Researcher handbook Investigator's Brochure (for unregistered drugs)

(4) Patient Information Sheet (Thai language)

(5) Summary of the research project (Thai language)

(6) *Complete research project details (Thai or English)*

(7) *Documents for quality control and drug*

production (8) *Documents authorizing research from the Human Research Ethics Review Committee (Institutional Review Board: IRB or Independent Ethics Committee: IEC) at the committee office food and drug* accepted

7. Details of the drug

No.	Drug name or drug code	Active Ingredients	quantity per unit
1			
2			
3			
4			

(If there are more details Please attach additional documents with the same format. which has the number of.....pages)

(signature) ---------- Applicant

(----------)

Note: Put a mark ÿ in the box ÿ in front of the desired message.

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Appendix 3

Summary of the research project (Thai language)

TFDA CT no.	
date of receipt	

I hereby certify that the information on the research project or the research project summary (Thai language) as shown in the table below is true, as this document

[..] is the first time that the research project information has been provided as of ... .

[..] This is an update of the research project information specified on the date of ..... (with updated information displayed)

If there is a change of information provided. I will update the document and submit it to the Food and Drug Administration.

as soon as possible

sign …… Eligible person submitting request/ attorney

(……..……) Print

Date of certification.....

Summary of the research project (Thai language)		
1.	research project name Thai language	
2.	research project name English	
3. The project code, i.e. the code set by the sponsor, should be The code used is the same across all research sites of the same protocol.		
4. The abbreviated name of the project or other names [..] are: .... [..] There [..] do not have		
5. US FDA IND number	are .... [..] do not have	
6. Clinical Trials Registration Registry) (may be registered with a Thai or foreign Registry) one of them)	*(Please specify Registry name and URL e.g. Thai Clinical Trial Registry(http://www.clinicaltrials.in.th/), ClinicalTrials.gov, etc. along with registration number)*	
7. Types of research projects (1-4 definitions) According to ICH-E8 'General Consideration for Clinical Trials')	distance: [..] 1 (Do the first research on people? [..] Yes [..] No) [..] 2 [..] 3 [..] 4 [..] Bioequivalent	
8. Types of Research Support	[..] A research project initiated by a pharmaceutical company. [..] A research project initiated by the researcher himself.	
9. Countries conducting research 10.	[..] Only in Thailand [..] Research in many countries	
Total number of institutions participating in research around the world.		
11. The total number of volunteers worldwide as planned.		
12. Number of research institutes in Thailand as planned		
13. Information of each research site in Thailand		

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Summary of the research project (Thai language)		
research site name	Number of volunteers Each research location	Principal investigator's name, address, contact telephone number, e-mail address
(1)		Name of Principal Investigator Address phone. Email
(2) *add/remove rows as appropriate* 14. Thai		
Sponsor	Name of organization Address Tel. Email/Website	
15. Research sponsors abroad (Foreign Sponsor)	Name of organization Address Tel. Email/Website	
16. Companies or agencies that supervise research (Monitor)	[ ] Applicant [ ] Not Applicant Name of Agency Address Tel. Email/Website [ ]	
17. Companies or administrative agencies Manage research projects (Project Management)	Applicant [ ] Not Applicant Name of Organization Address phone. Email/Website	
18. Companies or entities that administer Data Management (Data Management)	[ ] Applicant [ ] Not Applicant Name of Agency Address phone. Email/Website	

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Summary of the research project (Thai language)

19. Clinical laboratory Laboratory)	[ ] Use clinical laboratories of each research site. [ ] Use external clinical laboratories in research sites in the country / outside the country, including 1. Organization name address phone. Email/Website 2. Name of organization address phone. Email/Website

20. List of drugs used in the project (List all drugs used in the project, including investigational drugs, comparator/placebo drugs, and and medicines used together regardless of whether permission is granted in this request).

Common name, strength, form drug	Trade name	another name	the dose given, and Washout Period(if any)	Choose only 1
(1) *FDAmycin 10 mg.*		*SOS-001*	*20 mg every 12 hours*	[/] Research medicine [..] comparative medicine [..] Combination drugs
(2) *Placebo*			*2 tablets every 12 hours.*	[..] research drug [/] comparative medicine [..] Combination drugs
(3) *Paracetamol 500 mg.*	*TYLENOL acetaminophen 500 mg every 6 hrs.*			[..] research drug [..] comparative drugs [/] Combined drugs
(4) *Add/decrease rows according to needs.* *appropriate*				

21. Types of investigational drugs Project principles	Choose 1 option [ ] Vaccines [ ] Biological drugs [ ] Chemical	[ ] Vaccines for animals [ ] Biological medicines for animals [ ] Chemical drugs for animals
drugs 22. Start date of research in Thailand (approximately)		
23. End date of research in Thailand (estimated)		
24. How to find volunteers [..] Post advertisements.	[..] invite verbally [..] Others, please explain.....	

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Research Project Summary (Thai		
25. Financial support		**language)** Please specify all documents showing evidence [..] Research protocol (please specify document name, version, date, page, item) [..] Volunteer Documentation (please specify document title, version Date, page, clause) [..] Other, please specify and attach
26. Evidence showing insurance or Compensation if the subject suffers illness, injury, disability or death as a result of the clinical		a copy of the document. Please provide all documents showing proof of [..] insurance. [..] Documents for volunteers (please specify document title, version, date, page, item) [..] Others, please specify and attach a copy of the document.

trial. Note: Please tick ÿ in [ ] or fill in the statements that match the facts.

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Appendix 4

Certificate of Compliance with Terms and Conditions Regarding Importing or Ordering Drugs into the Kingdom for clinical research For applicants applying for N.Y.M.1

I..... ....

On behalf of ……..……. has submitted an application for permission to bring or order drugs for research (Nor.M.Y.

1) For the research project name (Thai language) ....

……

research project code ....to be carried out in a research facility and under the supervision of

Human research ethics review committee accepted by the Food and Drug Administration as follows:

at	Research site (name and address)	Name of the review committee research ethics in office people Food and Drug Administration Accept (please provide full name)	consideration status	
			wait	approve date
1.	(Rows can be increased or decreased depending on the number of research sites.)		[.]	[.] ……
2.			[.]	[.] ……
3.			[.]	[.] ……

I hereby promise that

1. Acknowledgment and will comply with the terms and conditions specified in Announcement of the Food and Drug Administration Re: Requirements for importing or ordering drugs into the Kingdom for clinical research and announce the relevant drug divisions

2. Will comply with the Drug Act B.E. 2510 and related regulations.

3. To revise relevant documents according to the opinions of the Food and Drug Administration and the Board. Consider the ethics of research in people recognized by the Food and Drug Administration. and submit the results of the committee's consideration.

Consider the ethics of research on such human subjects consistent with the research sites listed in the table above as soon as possible. with attached documents

All amendments to the Food and Drug Administration.

Improved to be clearly informed.

4. However, I and those involved will not begin the clinical research process at the said research site. until approved From the Human Research Ethics Committee accepted by the Food and Drug Administration.

I will comply in all respects with the representations given. If I do not comply in any case or false documents I agree to allow the Food and Drug Administration to revoke my application/licence, and I may be subject to

Prosecuting for making false reports to officials or for other offenses under relevant laws

Therefore, the name is important to the staff.

sign .... testimonial

(..... .....) (applicant)

Business operators or top executives of the Thai Red Cross Society/Phor Por./Ministries and Departments in charge of preventing and treating diseases

certification date .....

Note: Please tick ÿ in [ ] or fill in the text that matches the facts.

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Appendix 5

Certificate of Compliance with Terms and Conditions Regarding Importing or Ordering Drugs into the Kingdom for clinical research for the principal investigator

I..... ..... As the main investigator at the research site..... ..... of the research project name (Thai language) ....

.....

research project code .... Which the person who has the right to submit an application for permission to bring or order drugs for research (Nor.Yor.Mor.1 form) on behalf of .... has submitted an application related to the said research project The Food and Drug Administration

I hereby promise that: 1. I

will cooperate with the person who has the right to submit the request. To comply with the terms and conditions specified in office announcement 2. To conduct clinical research in accordance with the guidelines of good clinical research practice. (GCP) 3. The drug will only be used in research according

to the research program of the above research program authorized by the Secretary-General of the Committee. 4.

Will revise documents related to the above research project according to the opinion of the Food and Drug Administration. and the Human Research Ethics Committee

recognized by the Food and Drug Administration. and submit the results for consideration of the research ethics committee in such people for those who have the right to submit the above request to be submitted to the Office. Food and Drug Administration according to regulations

5. Documents related to the improved research project shall be used in the conduct of the research only after receiving approval from the The Human Research Ethics Review Committee has been accepted by the Food and Drug Administration.

6. Facilitate the staff of the Food and Drug Administration in inspecting the research (Inspection) both before the research. during the research 7. The clinical trial process of the above trial will not begin in my research site until:

Approved by the Human Research Ethics Review Board of the Food and Drug Administration. And is allowed to bring or order drugs into the kingdom for research purposes only I will comply in all respects with the representations given.

If I do not comply in any case Office of the Food and The drug may issue an order to suspend the research or to suspend the use of the drug. As appropriate to the case

Therefore, the name is important to the staff.

sign .... testimonial

(..... .....) (Principal Investigator)

Site..... ..... Certification

date..... .....

Note: Please tick ÿ in [ ] or fill in the text that matches the facts.

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Appendix 6

Application form for a specific waiver of drug label requirements

Please study the details of the requirements on labels for all sizes and the conditions for requesting a waiver of label requirements. Drug is a specific case in the annex to the Notification of the Division of Drugs on the details of requirements relating to the importation or prescription of drugs into Kingdom for Clinical Research or the details of the requirements for the production of modern sample drugs for Latest clinical research

1. General information 1.1.

Information on those eligible to submit an	
application Name of	
the applicant on behalf of	
1.2. Clinical trial data Research Project Name	
(Thai) Research Project Code	

2. Details of the request for a waiver as a specific case *(according to the terms and conditions detailed in the annex to the announcement of the Drug Division)*

2.1. Drug name as specified in the	
request 2.1.1. Explanation of the request for a waiver	
2.1.2. Necessity reasons	
2.1.3.Attach supporting documents as follows: 1. 2.	

Note: A similar table may be added for each drug entry.

3. Testimonials

I will consider the rights, safety and well-being of volunteers. as well as research results A reliable clinic is important and will supervise those involved in following the details that have been informed to the Food and Drug Administration.

and medicine

sign .... (applicant of waiver)*

(.....)

position ....

date ....

* The applicant for a waiver is according to the person who has the right to apply for the relevant Nor.Mor.1 or Por.Mor.8 permits.

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Appendix 7

A summary form for quality control documents and drug production classified by drug I hereby

certify that the information in the Evidence Summary Form, quality control document and pharmaceutical production is classified by drug. The table below is true by this document.

[..] It is the first time that the drug information is provided as of .....

[..] It is an update of the drug information that Indicated as of date ..... (with updated information displayed)

If there is a change of information provided. I will update the document and submit it to the Food and Drug Administration. as soon as possible

sign …… Eligible person submitting request/ attorney

(……) Print date of certification..... .....

[ ] Research drug, item no. ..... **[ ] comparative drugs** item ..... **[ ] combination drug** item	
1. Trade name of Drug Product 2.	
Common name of Drug Substance or other name (such as code)	
3. Dosage form and strength	
4. Treatment group	
5. Type of medication [ ] **Category 1** new drug that has not been clinically studied before [ ] **Category 2** new drug that has Phase 1, 2 or 3 clinical trials [ ] **Category 3** drug that has been registered formulation drug (Thai or foreign), but is conducting clinical research to study indications New, new drug administration method or new forms of drugs, etc. [ ] **Category 4** drugs that have been registered in the drug formula (Thai or foreign) but used in this research project for medicine, research, comparative medicine. or concomitant drugs in indications, method of drug administration or form of medicine that has already been registered 6. Manufacturer	
of the medicine to be imported (name, address, country)	
7. Sponsor (name, address, country) 8.	
Which country is the batch of drug imported from? 9. The	
status of the drug formula registration in the country according to Article	
8 attach ***Choose one of the four options whose manufacturer matches the one confirmed in section 6 and also matches the EXCEL file for the logistic system.**	[ ] NCE [ ] Refer to the registration of drug formulas in Thailand (Registration certificate number..... .....) [ ] CPP / CFS with GMP certification and confirmation sell [ ] Other evidence showing registration from the agency Drug Regulatory Notes 1)

Add the same table for each drug. 2) Please mark ÿ in [ ]. 3) Fill in the information that matches the facts.

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Appendix 8

Evidence of drug quality data NCE (New Chemical Entity)

I hereby certify that the information in the attached NCE (New Chemical Entity) drug quality evidence is Truth by this document

[..] It is the first time that the drug information is provided as of .....

[..] This is an update of the drug information specified on the date of ..... (with updated information displayed)

If there is a change of information provided. I will update the document and submit it to the Food and Drug Administration.

as soon as possible

sign …… Eligible person submitting request/ attorney

(……..……) Print

Certification date.....

list of topics	Minimum Required Topics for research phase		
	1, BE	2	3, 4
DRUG SUBSTANCE (NAME, MANUFACTURER)	ÿ ÿ ÿ		
S.1 General Information (name manufacturer)	ÿ ÿ ÿ		
S.1.1 Nomenclature (name, manufacturer)	ÿ ÿ ÿ		
- Recommended International Non-proprietary name (INN)	ÿ ÿ ÿ		
Compendial name, if relevant	- ÿ ÿ		
Chemical name(s)	- ÿ ÿ		
- Company or laboratory code	ÿ ÿ ÿ		
Other non-proprietary name(s) (e.g., national name, USAN, BAN)	- ÿ ÿ		
Chemical Abstracts Service (CAS) registry number	- ÿ ÿ		
S.1.2 Structure (name, manufacturer)	ÿ ÿ ÿ		
- Structural formula, including relative and absolute stereochemistry	ÿ ÿ ÿ		
- Molecular formula	ÿ ÿ ÿ		
- Molecular mass	ÿ ÿ ÿ		
S.1.3 General Properties (name, manufacturer)	ÿ ÿ ÿ		
Physical description (e.g., appearance, colour, physical state)	ÿ ÿ ÿ		
Physical form (e.g., preferred polymorphic form, solvate, hydrate)		- ÿ	
Solubilities (eg. solubility profile, tabular format, reporting in (mg/mL)	ÿ ÿ ÿ		
- pH and pKa values	ÿ ÿ ÿ		
- Other relevant information	ÿ ÿ ÿ		
S.2 Manufacture (name, manufacturer)	ÿ ÿ ÿ		
S.2.1 Manufacturer(s) (name, manufacturer)	ÿ ÿ ÿ		

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<table>
<tr><th rowspan="2">list of topics</th><th colspan="3">Minimum Required
Topics for research phase</th></tr>
<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td>- Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in the manufacturing of the batches to be used in this clinical trial</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">S.2.2 Description of Manufacturing Process and Process Controls (name, manufacturer) ý ÿ ÿ</td></tr>
<tr><td>- Flow diagram of the synthetic process(es)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Narrative description of the manufacturing process(es)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>S.2.3 Control of Materials (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- For drug substances or drug substance manufactured with reagents obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), provide an attestation (with supporting documentation, if applicable) confirming that the material is free of BSE/TSE agents</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Information on starting materials</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>S.2.4 Controls of Critical Steps and Intermediates (name, manufacturer)</td><td></td><td>- ÿ</td><td></td></tr>
<tr><td>- Summary of the controls performed at critical steps of the manufacturing process and on intermediates</td><td></td><td>- ÿ</td><td></td></tr>
<tr><td>S.3 Characterisation (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>S.3.1 Elucidation of Structure and other Characteristics (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>List of studies performed (e.g., IR, UV, NMR, MS, elemental analysis) and summary of the interpretation of evidence of structure</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Discussion on the potential for isomerism and identification of stereochemistry (e.g., geometric isomerism, number of chiral centres and configurations)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Summary of studies performed to identify potential polymorphic forms (including solvates), if available</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Summary of studies performed to identify the particle size distribution of the drug substance, if available</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Other characteristics</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>S.3.2 Impurities (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Identification of potential and actual impurities arising from the synthesis, manufacture and/or degradation</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>List of drug-related impurities (e.g., starting materials, by-products, intermediates, chiral impurities, degradation products, metabolites), including chemical name and origin
<table><tr><th>Drug-related Impurity (chemical name or descriptor)</th><th>Structure</th><th>Origin</th></tr><tr><td></td><td></td><td></td></tr></table></td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
</table>

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list of topics	Minimum Required Topics for research phase		
	1, BE	2	3, 4
List of process-related impurities (e.g., residual solvents, reagents, catalysts), including compound name and step used in synthesis	ÿ ÿ ÿ		
- Actual levels of impurities (e.g., drug-related and process-related) found in batches to be used in this clinical trial	ÿ ÿ ÿ		
S.4 Control of the Drug Substance (name, manufacturer)	ÿ ÿ ÿ		
S.4.1 Specification (name, manufacturer)	- ÿ ÿ		
Specification for the drug substance	- ÿ ÿ		
S.4.2 Analytical Procedures (name, manufacturer)	- ÿ ÿ		
- Summary of the analytical procedures (e.g., suitability, key method parameters, conditions)	- ÿ ÿ		
S.4.3 Validation of Analytical Procedures (name, manufacturer)	- ÿ ÿ		
Tabulated summary of the validation information (e.g., system suitability testing, validation parameters and results)	- ÿ ÿ		
S.4.4 Batch Analyses (name, manufacturer)	ÿ ÿ ÿ		
Description of the batches to be used in this clinical trial	ÿ ÿ ÿ		
Summary of results for the batches to be used in this clinical trial (should include tests, types of analytical procedures (e.g., HPLC, GC), and actual results)	ÿ ÿ ÿ		
S.4.5 Justification of Specification (name, manufacturer)	- ÿ ÿ		

Impurity (drug-related and process-related)	Acceptance Criteria	Results (include batch number and use) (e.g., clinical)		

Test	Acceptance Criteria	Analytical Procedure (Type and Source)

Batch Number	Batch Size	Date of Manufacture and Site of Production	Use (e.g., clinical)

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<table>
<tr><th colspan="2" rowspan="2">list of topics</th><th colspan="3">Minimum Required Topics for research phase</th></tr>
<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td></td><td>Justification of the drug substance specification (e.g., manufacturing experience, stability, historical batch analysis results, safety considerations)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.6 Container Closure System (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Description of the container closure system(s) for the storage and shipment of the drug substance</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.7 Stability (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.7.1 Stability Summary and Conclusions (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- Summary of stability studies to support this clinical trial (e.g., studies conducted, protocols used, results obtained)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Proposed storage conditions for the drug substance</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.7.2 Stability Protocol and Stability Commitment (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>If full long term stability data is not available at the time of filing, provide a summary of the stability protocol and a commitment for the continued monitoring of the drug substance stability according to the protocol</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.7.3 Stability Data (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- The actual stability results (i.e., raw data) may be found in</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.S.4 (e.g., analytical procedures used only for stability studies)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">DRUG PRODUCT (NAME, DOSAGE FORM)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.1 Description and Composition of the Drug Product (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Description of the dosage form</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Composition of the dosage form</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Composition, i.e., list of all components of the dosage form, and their amounts on a per unit basis (including overages, if any)
<table>
<tr><th rowspan="3">Component and Quality Standard (and Grade, if applicable)</th><th rowspan="3">Function</th><th colspan="4">Strength (label claim)</th></tr>
<tr><th></th><th></th><th></th><th></th></tr>
<tr><th>Quantity per unit</th><th>%</th><th>Quantity per unit</th><th>%</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Total</td><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Composition of all components that are mixtures (e.g., colorants, coatings, capsule shells, imprinting inks)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Description of accompanying reconstitution diluent(s), if applicable</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
</table>

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list of topics		Minimum Required Topics for research phase		
		1, BE	2	3, 4
·	Type of container closure system used for accompanying reconstitution diluent(s), if applicable	ÿ ÿ ÿ		
·	Qualitative list of the components of the placebo samples to be used in this clinical trial, if different from the components listed in 2.3.P.1(b)	- ÿ ÿ		
P.2 Pharmaceutical Development (name, dosage form)		ÿ ÿ ÿ		
·	Discussion on the development of the dosage form, the formulation, manufacturing process, etc	- ÿ ÿ		
·	For sterile, reconstituted products, summary of compatibility studies with diluents/containers	ÿ ÿ ÿ		
P.3 Manufacture (name, dosage form)		ÿ ÿ ÿ		
P.3.1 Manufacturer(s) (name, dosage form)		ÿ ÿ ÿ		
·	Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in the manufacturing of the batches to be used in this clinical trial	ÿ ÿ ÿ		
·	Attestation that the dosage form was manufactured under Good Manufacturing Practices (GMP) conditions	ÿ ÿ ÿ		
P.3.2 Batch Formula (name, dosage form)		ÿ ÿ ÿ		
·	List of all components of the dosage form to be used in the manufacturing process, and their amounts on a per batch basis (including overages, if any)	ÿ ÿ ÿ		

Strength (label claim)	
Batch Size(s) (number of dosage units)	
Component and Quality Standard (and Grade, if applicable)	Quantity per batch
Total	

P.3.3 Description of Manufacturing Process and Process Controls (name, dosage form)		ÿ ÿ ÿ		
·	Flow diagram of the manufacturing process	ÿ ÿ ÿ		
·	Detailed narrative description of the manufacturing process, including equipment type and working capacity, process parameters	- ÿ ÿ		
·	For sterile products, details and conditions of sterilization and lyophilization	ÿ ÿ ÿ		
P.4 Control of Excipients (name, dosage form)		ÿ ÿ ÿ		
P.4.1 Specifications (name, dosage form)		ÿ ÿ ÿ		
P.4.5 Excipients of Human or Animal Origin (name, dosage form)		ÿ ÿ ÿ		
·	List of excipients that are of human or animal origin (including country of origin)	ÿ ÿ ÿ		

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<table>
<tr><th rowspan="2">list of topics</th><th colspan="3">Minimum Required
Topics for research phase</th></tr>
<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td>- Summary of the information (e.g., sources, specifications, description of the testing performed, viral safety data) regarding adventitious agents for excipients of human or animal origin</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>For excipients obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), provide an attestation (with supporting documentation, if applicable) confirming that the material is free of BSE/TSE agents</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.4.6 Novel Excipients (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Summary of the details on the manufacture, characterization, and controls, with cross references to supporting safety data (nonclinical and/or clinical) on novel excipients</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5 Control of Drug Product (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5.1 Specification(s) (name, dosage form)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Specification(s) for the drug product<table><tr><th>Test</th><th>Acceptance Criteria</th><th>Analytical Procedure
(Type and Source)</th></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr></table></td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5.2 Analytical Procedures (name, dosage form)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Summary of the analytical procedures (e.g., key method parameters, conditions, suitability)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5.3 Validation of Analytical Procedures (name, dosage form)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Tabulated summary of the validation information (e.g., system suitability testing, validation parameters and results)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5.4 Batch Analyses (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Description of the batches to be used in this clinical trial (or representative batches)<table><tr><th>Strength and
Batch Number</th><th>Batch
Size</th><th>Date of Manufacture
and Site of Production</th><th>Input Drug
Substance Batch</th><th>Use (e.g.,
clinical)</th></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table></td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Summary of results for the batches to be used in this clinical trial or representative batches (should include tests, types of analytical procedures (type and source), and actual results)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5.5 Characterisation of Impurities (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
</table>

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<table>
<tr><th colspan="2" rowspan="2">list of topics</th><th colspan="3">Minimum Required Topics for research phase</th></tr>
<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td></td><td>Information on the characterization of impurities, not previously provided in S.3.2 (e.g., summary of actual and potential degradation products)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.5.6 Justification of Specification(s) (name, dosage form)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Justification of the drug product specification (e.g., manufacturing experience, stability, historical batch analysis results, safety considerations)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.7 Container Closure System (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Description of the container closure systems, including unit count or fill size, container size or volume</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Materials of construction of each primary packaging component</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>For sterile products, details of washing, sterilization and depyrogenation procedures for container closures</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.8 Stability (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.8.1 Stability Summary and Conclusions (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- Summary of stability studies to support this clinical trial (e.g., studies conducted, protocols used, results obtained)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Description of stability study details
<table>
<tr><th>Storage Conditions (°C, % RH, light)</th><th>Strength and Batch Number</th><th>Batch Size and Date of Manufacture</th><th>Container Closure System</th><th>Completed (and Proposed) Test Intervals</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Summary and discussion of stability study results</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Proposed storage conditions and shelf life (and in-use storage conditions and in use period, if applicable)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="5">P.8.2 Post-approval Stability Protocol and Stability Commitment (name, dosage form) ÿ ÿ ÿ</td></tr>
<tr><td></td><td>If full long term stability data is not available at the time of filing, provide a summary of the stability protocol and a commitment that the stability of the clinical trial samples or representative batches will be monitored throughout the duration of the clinical trial or proposed shelf life</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.8.3 Stability Data (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- The actual stability results (i.e., raw data) may be found in</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.P.5 (e.g., analytical procedures used only for stability studies)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
</table>

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ATTACHMENTS

Attachment Number	Subject

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Appendix 9

Form of certificate of a pharmaceutical product

Certificate of a Pharmaceutical ProductP1P

This certificate conforms to the format recommended by the World Health Organization

(general instructions and explanatory notes attached).

Certificate No: _____

Exporting (certifying) country: _____

Importing (requesting) country: _____

1. Name and dosage form of product:

_____

1.1 Active ingredient(s)P 2 P and amount(s)P 3 P per unit dose :

_____

_____

For complete composition including excipients, see attached.P4

1.2 Is this product licensed to be placed on the market for use in the exporting country?P 5

oYes o No

1.3 Is this product actually on the market in the exporting country?

o Yes o No o unknown

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B.P 6

2A.1 Number of product licenseP7 Pand date of issue :

_____

2A.2 Product-license holder (name and address):

Name: _____

Address: _____

2A.3 Status of product-license holder:P 8

of at o c

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are : P 9

Name: _____

Address: _____

2A.4 Is Summary Basis of Approval appended?P10 P

o Yes o No

2A.5 Is the attached, officially approved product information complete and consonant with the license? P 11

(yes/no/not provided)

o Yes o No o Not provided

2A.6 Applicant for certificate, if different from license holder (name and address) :P12

Name: _____

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Address: _____

2B.1 Applicant for certificate (name and address) :

Name: _____

Address: _____

2B.2 Status of applicant :P8

of at o c

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are :P

Name: _____

Address: _____

2B.3 Why is marketing authorization lacking?

o not required o under consideration

o not requested o refused

2B.4 Remarks :P13

_____

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?P14P

o Yes o No she has

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years) : _____

3.2 Has the manufacture of this type of dosage form been inspected?

o Yes o No

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?P 15

o Yes o No she has

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?P16

If no explain: _____

Address of certifying authority:

_____

Telephone number: _____

Fax number: _____

Name of authorized person:

_____

Signature of authorized person:

_____

Stamp and date:

_____

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Explanatory notes

1 This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2 Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

3 The formula (complete composition) of the dosage form should be given on the certificate or be appended.

4 Details of quantitative composition are preferred, but their provision is subject to the agreement of the product license holder.

5 When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license.

6 Sections 2A and 2B are mutually exclusive.

7 Indicate, when applicable, if the license is provisional, or the product has not yet been approved.

8 Specify whether the person responsible for placing the product on the market :

(a) manufactures the dosage form;

(b) packages and/or labels a dosage form manufactured by an independent company; or

(c) is involved in none of the above.

9 This information can be provided only with the consent of the product-license holder or, in the case of non registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.

It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.

10 This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

11 This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).

12 In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.

13 Please indicate the reason that the applicant has provided for not requesting registration :

(a) the product has been developed exclusively for the treatment of conditions - particularly tropical diseases - not endemic in the country of export;

(b) the product has been reformulated with a view to improving its stability under tropical conditions;

(c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;

(d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;

(e) any other reason, please specify.

14 Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15 The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to

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biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

16 This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

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Appendix 10

Certificate of Free Sale Requirements 1. CFS letter must be issued by the country of origin or the country of sale certified by the Food and Drug Administration. CFS letter issued by the country of sale by the Food and Drug Administration. guarantee 1.1 The country of origin is the owner of the product, and the country of origin has been contracted to manufacture the product on its behalf;

1.2 The country of origin does not sell the product because there is no need to use the product; or 1.3 Other cases as The Food and Drug Administration deems appropriate.

2. In case the CFS letter is issued by the selling country 2.1 Certificate of origin from the country of manufacture. 2.2 For pharmaceutical and food products, the following documents must be attached. that specifies the quality certificate of the production source according to international standard

2.2.2 Certificate of product standard that has the same quality as products sold in 3. The CFS under clause 1 and the certificate under clause 2.1 and clause 2.2.1 must be issued or certified by the relevant government agency. It is responsible for supervising the health products of that kind. 4. The CFS letter must include the following details:

4.1 Name of the product; 4.2 Name of the producer and location; 4.3 Meaningful statements certifying that "Available in the country of issue" 4.4 Other statements as specified by each product division, such as -

Pharmaceutical products specify the main active ingredient and quantity - Medical devices specify the model (model) or individual products as well 5. Text in the book CFS if in another language In addition to English, it shall be translated into Thai or English with Reliable agency certification

6. In case of using a copy of the CFS instead of the original, the statement must be certified by a government agency or private agency 7.

In the case of multiple products using the same CFS, the original CFS must be submitted together with 8. The CFS shall be valid within the period specified in the CFS, and in the event that the validity period is not specified, the CFS shall be submitted within 2 years from the date of issuance of the CFS.

Notes according to the order of the office No. 398/2544 dated October 4, 2001, amended according to the SEC Order No. 122/2548 dated February 25, 2005. and amended according to the order of the Office No. 477/2006, dated 29 September 2549

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Appendix 11 (Revised 7 Aug. 23)

Self-examination form for

Application for permission to bring or order drugs into the kingdom for research purposes

(Nor.Mor.1 form)

check number	
date	
project code	
TFDA CT no.	

Part 1 Summary of the document examination results (Only for officers) when requesting permission of the same project

Type of research drug (main body) [ ] Biotherapeutic drug [ ] Phase 1 research drug	[ ] Animal medicine [ ] Other	**quality data type** [ ] CMC (at least 1 drug) [ ] Registration reference (all)	**In case CMC has received Have you ever granted permission?** [ ] Yes [ ] No

Summary of document review results [ ] Accepting the request (issuing a document "Notification of the Result of the Request") [ ] cannot be amended on the date of application submission (issuing a document "Memorandum of Deficiency")	**inspector** ( ) dated

Part 2 Instructions and Procedures

!! Please read!!

Guidelines for using the self-check form for submitting documents 1. Study the details of the terms and conditions in **the announcement of the Food and Drug Administration and the relevant announcement of the Division of Drugs .** 2. Read instructions and testimonials. and fill **in** the information in part 3 and part 4

- Answer **'Yes'** or **'Yes'** or ÿ means self-audit and complies with the requirements - Answer **'N/A'** or **'Not Applicable'** after checking and found that the requirements indicate that this document is not required to be submitted - Answer **'Refer...'** or **'Refer...' ,** specify the request number or request number + date received Related

Part 3 Certification of Document Preparation

Eligible person/Authorized person .... On behalf of (agency) .... Tel ……...……..……Fax..……...……..……..……E-mail: … ……...……...

I hereby certify that I have studied and prepared documents according to the requirements of the FDA (such as announcements of the Food and Drug Administration and Announcement of the relevant Drug Division) together with submitting a Nor.Yor.Mor. 1 form, all other documents. Sorted by document list and checked by yourself according to the table in section 4.

sign …… (Eligible person/Authorized person) Date.....

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Section 4 Checklist of documents

Clause	list of documents	results check too myself	Results of inspection by officer # 1	# 2	note
*	sign the certification or certify true and complete copies				
**	the same research project Someone has applied for permission to be my agency Only one agency in Thailand (only for new projects from October 1, 2016)				
1	**About submitting this request(please fill in information)**				
	times of applying for permission of the same project				
	[ ] Submitted after all ECs approve, or [ ] in parallel awaiting EC results.				
	Please indicate the primary investigational drug used for the primary purpose of the study. This research project is the item that..... which is classified as a drug [ ] Biotherapeutic drug [ ] Veterinary [ ] Phase 1 research drug [ ] other				
2	drug **Data recording device** (only for paper submission)				
	2.1 Copy of all submitted documents (PDF file)				
	2.2 Data template files				
	3.3 The manufacturer on file corresponds to the manufacturer notified in Form 11.1.				
3 forms, Nor.Mor.1	☐ e-sub paper (☐ only necessary and approved by the officer)				
	3.1 In the case of e-sub, it will create a request in the system.				
	1) The name of the Thai research project corresponds to the EC approval or in the case of parallel submission. to match the research project summary (Thai language)				
	3.2 In case of submitting a paper form Submit 2 sets of copies with original signatures + complete information				
	1) Same as the prototype form announced by the Ministry of Public Health.				
	2) Signed by the authorized person. With 2 real signatures				
	3) The list of drugs complies with Template **3.3, the**				
	Act of Assignment of Substitutes. In the event that the top executive of ministries, departments in charge of preventing and treating diseases, Thai Red Cross Society or the Pharmaceutical Organization There is an assignment to perform duties on behalf of Related to bringing or ordering drugs into the Kingdom				
4	**Summary of the research project (Thai language) according to the form prescribed by the FDA** (fill in system information)				
	1) Name of the research project in Thai				
	2) Name of the research project in English				
	3) Project code (should be the same for all research sites of same research framework)				
	4) Project abbreviation or other name.				
	5) US FDA IND number				
	6) Clinical Trials Registry				
	7) Type of research project				
	8) Types of research support				

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Clause	list of documents	results Also check. myself	Examination results by staff # 1	# 2	note
	9) Study country 10) Total number				
	of research institutes worldwide 11) Total number of				
	subjects worldwide as planned 12) Planned number of				
	research institutes in Thailand 13) Information of each research site in				
	Thailand 14) Sponsors Research in Thailand 15) Research				
	sponsors abroad 16) Company or agency that				
	supervises research (Monitor) 17) Company or				
	agency that manages research projects (Project Management) 18)				
	Company or agency that manages Data management 19) Clinical laboratories 20) List of drugs used in				
	the project (both according to Nor.Mor.1 and domestic procurement)				
	21) Type of research drug of the project 22) Start date of				
	the trial in Thailand (approximately) 23) End of the trial in Thailand				
	(approximately)				
	24) How to Find Volunteers				
	25) Financial support + attached documents 26) Evidence of insurance or compensation if The subject's illness, injury, disability or death as a result of the clinical trial + Attach documents				
5	**Certification of compliance with the terms and conditions for the applicant Nov. 1**				
	1) The signatory is the same person who signed the Nor.Mor.1 form.				
	2) Research project code consistent with research protocol 3) EC				
	accepted by the FDA 4)				
	Complete information 5) Content				
	is as specified **Affidavit of Compliance**				
6	**with Terms and Conditions for the principal investigator**				
	1) The research project code corresponds to the research outline.				
	2) Complete information 3)				
	Contents as required 4) The primary				
	investigator fully certifies all research sites **7 drug labels for all**				
doses (Thai or English) :	1) Drug label ……..… 2) Drug label ……..…				
	7.1 Complete with all containers and sizes that have the same format as the label used. TRUE				
	7.2 Thai language is used , **except** drug names/codes. and information about research project sponsors, can use Thai or English and the case of drugs Drug administration by medical professionals Thai or English language can be used. **7.3**				
	Secondary labels consist of (at least) annexed to the				

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Clause	list of documents	results check too myself	examination results by officer # 1	# 2	note
	(1) drug name/drug code, strength, form, route of administration, unit quantity Count in the case of concealing the treatment stated: “placebo or [drug name/drug code] + [strength size]”				
	(2) research project code or research project name				
	(3) Lot number and/or code number to identify components and packaging.				
	(4) Volunteer number or treatment number and number Make an appointment (if relevant)				
	(5) Medication method may refer to specific documents to explain. to volunteers (e.g. medication records) or personnel who are pharmaceutical product executive				
	(6) name, address and telephone number of Sponsor/CRO/Researcher unless Volunteers receive identification cards showing these information (with document)				
	(7) Statement “For Clinical Investigation Use Only” (8) Storage				
	Conditions				
	(9) Specify use by date/expiration date/retest date (month/year).				
	(10) Statement of “keep out of reach of children” in Thai, except volunteers. Didn't bring medicine home				
	7.4 Primary label, in general, contains (at least)				
	(1) drug name/drug code, strength, form, route of administration, unit quantity Count in the case of concealing the treatment stated: “placebo or [drug name/drug code] + [strength size]”				
	(2) research project code or research project name				
	(3) Lot number and/or code number to identify components and packaging.				
	(4) Volunteer number or treatment number and number Make an appointment (if applicable)				
	(5) Medication method may refer to specific documents to explain. to volunteers (e.g. medication records) or personnel who are pharmaceutical product executive				
	(6) name, address and telephone number of Sponsor/CRO/Researcher unless Volunteers receive identification cards showing these information (with document)				
	(7) Statement “For Clinical Investigation Use Only” (8) Storage				
	Conditions				
	(9) Specify use by date/expiration date/retest date (month/year).				
	(10) Statement of “keep out of reach of children” in Thai, except volunteers. I didn't bring the medicine home.				
	7.5 Primary label Where primary packaging is coexisting with secondary packaging. Phumsaer consists of (at least)				
	(1) drug name/drug code, strength, form, route of administration (except edible solids) Quantity unit count In case of concealing treatment, specify: “placebo or [drug name/code] + [strength dose]”				

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Clause	list of documents	results check too myself	Examination results by staff # 1	Examination results by staff # 2	note
	(2) trial code or trial name; (3) batch and/or code number to identify				
	ingredients and packaging; (4) subject number or treatment number. and appointment number (if				
	applicable). (5) Name of the Sponsor/CRO/Investigator. **7.6 Primary Label If the primary packaging is in blister form or a small unit**				
	which has an area of less than 3 square				
	inches and is located in conjunction with Secondary packaging always consists of (at least) (1) the dosing channel (except for oral solids); In case of disclosing treatment, specify: drug name/code and strength (2) trial code or trial name (3) batch and/or code number to identify				
	ingredients and packaging (4) subject number or trial number treat and appointment number (if applicable). (5) Name of Sponsor/CRO/Investigator **7.7 In the case of drug preparation for administration**				
	at the research site, new labeling is required on the packaging				
	to be administered (this is required, but not required to be submitted). (with request) (1) The label				
	is appropriate, accurate, and meets the objectives. (2) There is an SOP or standard method in accordance with GMP. (3) Operated by qualified				
	and trained personnel. (4) There is evidence of				
	practice records. and inspection by a second party at least Under strict control. (5) Keep evidence and record documents to support the audit. **7.8 If necessary, Relaxation may be granted only in the following cases.**				
	☐ The information on drug labels in the MRCT is relaxed and cannot be changed in time upon submission. For the first time, pass the inspection and get into the system within 30 Apr. '21 - Request form for a waiver of drug label requirements for specific cases				
	☐ Waive information on labels that may refer to other documents, such as dosage instructions. Referring to medication records, etc. - Request form for a waiver of drug label requirements for specific cases - Referenced documents include				

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Clause	list of documents	results check too myself	Examination results by staff # 1	Examination results by staff # 2	note
	☐ Additional labeling after the drug is brought into Thailand to comply with the **requirements licensed to produce the correct medicine]** - Request form for a waiver of drug label requirements for specific cases - Labels or label images that look like actual labels .... License to produce modern drugs number..... ..... - **or** in case of necessity request a waiver of labeling operations in The place that can be controlled according to the conditions instead by 1) **State the reason** and 2) Attach **SOP** [Appropriate personnel trained, procedures, records, second-party audits, strictly controlled. and comply with GMP] **drug documentation (For drugs that have been registered with drug formulas)**				
8	are: 6.1 Medicine documentation…….. 6.2 Accompanying document ……..				
	It belongs to the registered formula referred to in				
	clause 11* if it is in another language. To translate into Thai / English and certify that the language text Others correspond to				
9	Thai/English language* **Researcher's handbook Investigator's Brochure (for unregistered drugs)** Evidence				
	that an up-to-date Investigator's Guide was submitted to the Board. consider ethics (except parallel submission) Table of Contents				
	Summary Introduction				
	Physical, chemical, pharmaceutical properties and formulations. Results of non-				
	human studies (Animal Studies) 1. Pharmacology 2.				
	Pharmacokinetics and the				
	transformation process in Experimental animals				
	3. Toxicology				
	Results of human studies (Clinical Study) 1.				
	Pharmacokinetics and product conversion process				
	2. Safety and effectiveness				
	3. Experience in marketing				
	SUMMARY OF INFORMATION AND INSTRUCTIONS				
FOR Investigators	**10 Patient Information Sheet (Thai)** 1) Contains language appropriate to the				
	subject* 2) Approved by the EC (except for				
	parallel submissions) 3) Number of subjects Apply for				
	participation in the approximate research of the entire project. and the number of volunteers in each institution in Thailand (page.....)				

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Clause	list of documents	results check too myself	Examination results by staff		note
			# 1	# 2	
	4) It states that the FDA is supervising research. Research investigators, IRB/IEC and regulators will be allowed to Check the original medical records of the volunteers directly. (page.....)				
	5) Indicated as research 6)				
	Purpose of research 7) Treatment				
	provided and opportunity to be randomly selected 8)				
	Research methodology and invasiveness 9) Responsibilities of				
	subjects 10) 11) Potential risks or discomfort				
	to subjects. Or to the embryo or fetus or the				
	mother's milk. 12) Expected benefits 13) Alternative procedures or treatments; 14) Compensation and/or treatment to be received by subjects;				
	15) Compensation (if any) determined on a case-by-case basis. 16)				
	Expenses (if applicable) 17) State that the subject's				
	participation in the research is voluntary. and may refuse to				
	participate or withdraw from the research at any time. 18)				
	Provides that the subject's				
	personal information will be kept confidential and that such information will not be disclosed to the public beyond the scope permitted by law, even if Publication of research results 19) Specify that subjects or their legal				
	representatives will be notified. new information in due time which may affect the voluntary 20) Who to contact for more information about the trial and the rights of subjects, and who to be notified in the event of				
	potential harm. results of research				
	21) Circumstances/reasons that may lead to the withdrawal of the subject from the study				
	22) The expected duration of the subject's participation in the research				
11 Complete research project description (Thai or English)	1) EC approval				
	(except for parallel submission) 2) General information				
	3) Background				
	information 4) Objectives and aims of the				
	research 5) research design 6) subject selection and				
	subject withdrawal				
	7) Caring for volunteers 8)				
	Evaluation of effectiveness				
	9) Security Assessment				
	10) Statistics				
	11) Direct access to original data and original documents Attached				

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Clause	list of documents	results check too myself	Examination results by staff # 1	Examination results by staff # 2	note
	12) Quality Control and Quality Assurance of the Research 13) Research				
	Ethics 14) Data Management and Record				
	Retention 15) Financial Support and Assurance (If not specified				
	in this document, a separate agreement may be attached.)* 16) Research Publication Policy 17) Additional details 12 Quality Control				
	Documentation and Drug Manufacturing				
	11.1 Quality Control Document				
Evidence Summary Form **and pharmaceutical production**					
	Classified by drug list				
	- As for certification, fill out and sign completely. 11.2				
	Evidence of quality control and drug production documents				
	attached 1) **NCE for Phase .....** Drugs.....				
	- Testimonials section, complete and signed - The				
	manufacturer in the evidence is the same as the manufacturer reported				
	in Form 11.1 - GMP certificate issued by the government agency and has				
	not expired - Drug Substance contains complete information according to				
	the subsections specified - Drug Product has complete information				
	according to the subsections specified. 2) **Refer to the registration of drug formulas in Thailand.** (Certificate No. Registered.....) for drugs..... With				
	a copy attached - the manufacturer in the evidence is the same as the				
	manufacturer informed in Form 11.1 3) **Drug formula registration abroad** (CPP / CFS / evidence showing registration from the pharmaceutical regulatory agency) of the				
	drug.. ..... -				
	Has not expired - The source of production in the evidence				
	matches the drug to be imported for research - In case of showing evidence showing registration from the agency website drug supervision But the manufacturer is not found on the web/pharmaceutical leaflet/label, please attach a COA.				
13 Research authorization documents from the Human Research Ethics Review Committee, accepted by the Food and Drug Administration (of all Organization as specified in the regulations) 12.1 Name of organization…… 12.2 Name of organization…… …… (except parallel filing may not be available or not complete)					
	1) Thai version* 2) Name				
	of the IRB/IEC as approved by the FDA 3) Name of research				
	project 4) Name of				
	researcher 5)				
	Name of all approved research sites 6)				
	Documentation of research project and related documents, along with specifying the version (Version) approved by the Human Research Ethics Committee. Attached				

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Clause	list of documents	results check too myself	Examination results by staff		note
			# 1	# 2	
	7) Time period for research approval and/or expiration date				
14 documents for calculating the amount of medication					
	1) Based on the number of subjects requested for EC.				
	2) Calculate the dosage for the planned project period. 3) If the dosing period is				
	not specified in days, months or years. Of course, calculate not more than 4				
years **15 Power of Attorney** (Only in the case of paper submission)					
	1) Power of Attorney (submit application, clarify, amend, receive				
	documents) 2) Copy of ID card of attorney/passport 3) Copy of ID card of				
	attorney 4) Duty stamp 30 baht per attorney 16 Others				
	(if any) - Documents approved by the committee or academic				
sub-committee Associated with specially regulated research drugs, such as the AIDS vaccine, for example.					

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Appendix 12

Amendment/Additional Clarification Request Form

For the applicant/ attorney: I (name- surname)..... .... On behalf of.....	**Clinical Research Medicine Received date.....**
which is the applicant/ attorney for the application, Nor.Yor.M.1, receiving number at ……..Receiving date……..…….. and was informed to correct/ clarify Within the day ……..... Please clarify the issues by submitting the following documents:	**recipient.....**

document number	list of documents (Please prepare, certify and inspect the documents yourself.)	**for the applicant Check it yourself** (Answer ÿ means checked empty = not checked, will return)
*	Sign the certification or certify true copies on every copy of the document. Data recording	
1	device 1.1 [ ] A copy of all submitted documents (PDF file) 1.2 [ ] Excel file for the Logistic	
	system. (add list of documents as appropriate ready to	
2	check by yourself)	

I certify that I have clarified on various issues. according to the opinion of the appraisers along with submitting a set of documents, complete with all items that have been notified

for clarification/correction sign…… **(Applicant/Attorney)** dated.....

(.....)

Note: Please tick ÿ in [ ] or fill in the text that matches the facts.

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Appendix 13

Letter of submission of results of review from the Ethics Review Committee on Human Research

Company / department header

date..... ...

Subject Requesting the results of consideration from the Human Research Ethics Review Committee (After parallel filing)

Dear Director of the Drug

Division **Refer to** License to import or order drugs into the kingdom for research purposes. Pick-up

number at…… . **Attachments* (1 set) as follows:**

1. A copy of the license to import or order drugs into the kingdom for research purposes, receipt

number…… 2. Human Research Ethics Review Committee.....(name)..... Namely,

No. 2.1 Approval or results from the ethics review committee on research in human subjects.....(name).....

No. 2.2 Volunteer recommendation document..... (Revised Version) No.

2.3 ..... (Revised edition) 3. Human research ethics

committee.....(Name)..... namely

Number 3.1 ....

.... All file recording devices are the same as the documents submitted

this time. As permitted by the Food and Drug Administration.....<name of the company/agency>.....take or to order drugs into the Kingdom for research purposes (Form Nor Yor. M. 1), receipt number at ..... Date received..... For a research project in Thai name .... Research project code..... TFDA CT no. ..... (if any) as detailed in the attachment No. 1

I have now received the results of the review from the Ethics Review Committee on Human Research, and hereby submit the review and all relevant documentation as amended in the opinion of the The Food and Drug Administration and Human Research Ethics Committee are hereby accompanied. Approved [ ] Some research sites specified in the license Not approved: 1).....

and

2)..... I would like to inform the cancellation of the research facility. And certify that the drug will not be imported for use in research facilities that cancel

Please be informed accordingly.

Yours sincerely

.....

(.....)

position .....

Note: Signed by the authorized person according to the requirements in clause 1.1 and marked ý Related text pages and fill in the correct statement according to the facts

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Appendix 14

Progress report submission letter

Company / department header

date..... ...

Subject Request for submitting a research project progress report form ..... For the year ..... **Dear**

Director of Drug Division,

Refer to License to import or order drugs into the Kingdom for research purposes. *Pick-up number at…<fill in all*

requests>… **Attachments* (amount 1 set) as follows:**

No. 1, research project progress report form

number 2 .....

Number 3: File recording device that is the same as all documents submitted this

time. As permitted by the Food and Drug Administration.....<name of the company/agency>.....

Bringing or ordering drugs into the kingdom for research purposes (Nor.Yor.Mor.1 form) receipt number at ..... Received

date..... For the research project name.....<Thai name>..... ....

.....

Research project code..... TFDA CT no. ..... (if any) as detailed in the attachment No. 1

Now, I would like to submit a research project progress report as required in the announcement.

The relevant Food and Drug Administration and attached herewith.

Please be informed accordingly.

Yours sincerely

.....

(.....)

position .....

Note: Signed by the authorized person in accordance with clause 1.1 and filled in factually correct statement.

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Appendix 15

research project progress report form

research project progress report form That is allowed to bring or order drugs into the kingdom without registering a drug formula for research purposes	research project code ……	Page ..... of .....
	TFDA CT no.	data between dates ..... to .....

Refer to Nor.Yor.M.1 form, receiving number at ……<fill in all

requests>……..... authorized person .... (Please specify the name of the organization/company) [ ] Ongoing . Name of the research project in	Overall/global status of research projects [ ] Closed as scheduled. [ ] Closed ahead of schedule.

Thai. ....

.....

Research sponsor in Thailand Name .... address .... Phone/E-mail	Overseas research sponsor Name .... address .... Phone/E-mail	Contract Research Company (CRO) Name .... address .... Phone/E-mail	Research Supervisor (Monitor) Name- Surname .... affiliation .... Phone/E- mail ....

list of research sites	Principal Investigator's name	Number of volunteers (people)						Closing date Volunteers joining the project (or approximate) *a*	Last appointment date of last (or approximate) study subject *a*	status of Conduct research at each research site *b.*
1.										
2.										
3.										

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research project progress report form

That is allowed to bring or order drugs into the kingdom without registering a drug formula for research purposes

research project code ……

Page ..... of .....

TFDA CT no. .....

data between dates

..... to .....

N										

* Are there any changes? that fall under the scope of “4.3 in the event that a notification is required for information of the Food and Drug Administration” which has not yet been informed FDA or not

[ ] None . [ ] Yes (Attach the clarification letter and supporting documents)

** Are there any deviations from the research outline during this reporting period?

[ ] do not have . [ ] Yes (Attach the clarification letter and supporting documents)

*** If in doubt or there is a necessity/urgency concerning the research project

Please contact .... Responsibilities in the project are .....

Tel.....Fax..... .....E-mail.....

Additional Explanation

a If there is a reason that the last volunteer has not yet been identified, or the last volunteer has not yet been closed, state "Cannot be identified".

b e.g. "Cancelled due to lack of volunteers", "In progress", "Volunteers completed", "Closed. determined due to…” etc.

c Signed by the authorized person in accordance with the requirements in item 1.1 . Please check the mark ÿ in [ ] and fill in the factually accurate statement.

I certify that all information is true.

……

(.....)

position..... .....

As the operator/chief executive of the unit

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Appendix 16

Guidelines to take when changing

After obtaining permission to produce drug samples for human research studies or to import or order drugs Came to the kingdom for research. Drug-related or clinical trial-related changes may occur.

Permitted, the Division of Medicine has prepared a guideline for action when there is a change to be used as a guideline by dividing changed to 3 groups

1.	**Changes that must be notified** include:	for	
		Nov. 1	**Nov. 8***
(1)	Any information in the research project summary (except for the addition of research sites), with some It needs to be approved/approved by the EC that has been accepted by the FDA and attached. Evidence, such as the name of the research project in Thai or English Research Project Code Abbreviation Research project, or other title, principal investigator, or item that may result from change the research protocol	ÿ	ÿ
(2)	Research Proposal Documents Once approved/approved by the EC that is accepted by the FDA, except in the case of special conditions	ÿ	ÿ
(3)	Abolish or reduce research facilities	ÿ	ÿ
(4)	Investigator's manual or volunteer guide or documentation on Administer medications given to volunteers or insurance documents. upon approval/ Approved by the EC that the FDA has accepted	ÿ	ÿ
(5)	Permitted drug labels 1) In the event that the form has been changed but the text is still complete according to all requirements or 2) In the event that the name, address and telephone number of the research sponsor is corrected; or contract research organization or researcher; or 3) In case of correcting spelling mistakes In both cases, the licensee must inspect and certify by itself that it still complies. requirements and carry out labeling in a GMP certified facility.	ÿ	ÿ
(6)	Documentation In the event that academic information is updated according to the previous drug formula registration refer	ÿ	ÿ
(7)	Change the Drug Substance Manufacturer of Chemical Drugs in Quality Control Documentation and produce drugs, whereby the licensee must verify and certify themselves that this change does not reduce the quality of the drug	ÿ	ÿ

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1.	**Changes that must be notified** include:	for	
		Nov. 1	**Nov. 8***
(8)	Extending the shelf life of an investigational drug or placebo - a case where stability studies have been conducted The stability protocol was implemented and the analytical results were consistent with the stability specification. According to the latest permission, Nov. 1/ Nov. 8, by The licensee shall verify and self-certify that it complies with such conditions.	ÿ	ÿ
(9)	Notification of oversight of clinical trials conducted in Thailand by regulatory agencies Taking care of medicines from abroad (either in person or online) by must be notified as soon as known	ÿ	ÿ
(10)	notify the termination or termination of the research project before the time specified in the research project plan ready to inform the cause	ÿ	ÿ
(11)	Serious violations of Good Clinical Research Practice (ICH GCP) guidelines or research proposal or legal requirements which may affect safety or the well-being of volunteers or the scientific value of scientific research clinic, which must also inform the corrective and preventive measures (CAPA).	ÿ	ÿ

2.	**Changes that require a change request and allowed before proceeding ,** including	for	
		Nov. 1	**Nov. 8***
(1)	Add a research site without increasing the number of drugs requested to be imported or produced	ÿ	ÿ
(2)	Add or edit drug labels that are not subject to notification.	ÿ	ÿ
(3)	Drug quality and production control documents (1) in case of amending DS and DP manufacturers of biological drugs (2) Fix the DP manufacturer of chemical drugs.	ÿ	N/A
(4)	Extending the shelf life of an investigational drug or a placebo - a case study of drug stability, not It complies with the latest stability protocol ever allowed. Nov. 1/ Nov. 8	ÿ	ÿ
(5)	Use of drugs from a research site quota from a license at a research site another place which is not specified in the same license Even though it's a research study The same can apply for permission to change only in case of necessity. as well as certifying that evidence will be kept and accounts can be audited reversible	ÿ	N/A
(6)	Other changes that do not apply “Changes that must be notified” or “Changes that require a new request for approval Nov.Mor.1/ Nov.8”	ÿ	ÿ

3.	**Changes that must be submitted for a new approval Nov.Mor.1/ Nov.8** namely	**for**	
		Nov. 1	**Nov. 8***
(1)	Change the applicant company for the project (must cancel the original license)	ÿ	N/A

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3.	**Changes that must be submitted for a new approval Nov.Mor.1/ Nov.8** namely	**for**	
		Nov. 1	**Nov. 8***
(2)	Add a list of drugs or the number of drugs requested to be	ÿ	N/A
(3)	imported, change a drug formula or Product specification Increase	ÿ	ÿ
(4)	research facilities and increase the number of drugs requested for import or production.	ÿ	ÿ
(5)	want to produce a new original research drug for use in the original research project	N/A	ÿ
(6)	Use of previously licensed drugs for use in new clinical trials	N/A	ÿ

* Remarks on changes made in Por.Yor.8 for bioequivalence studies. If it does not qualify as "Change that must

Submit an application for a new production permit" allows the licensee to submit changes to the form for acknowledgment without having to ask for permission.

Before taking action, however, the licensee must keep records and documents to support the operation.

Check from the Drug Division or authorized person. and still has the duty to carry out various tasks for the consideration committee

Research ethics in people accepted by the FDA as before

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Appendix 17

self-examination form

For the request to amend the details regarding permission

according to Form Nor Yor. 1 / Por Yor. 8 for research studies in humans.

Request for amendment about	
[ ] Nov. 1 **[ ] Nov. 8 (research)**	
project code	
check number	
date	

Part 1 Summary of the document examination results (Only officers)

Type of research drug (main body)

[ ] Biological drug [ ] Animal medicine [ ] Chemical drugs [ ] other

Summary of document review results	**inspector**
[ ] Accepting the request (issuing a document "Notification of the Result of the Request") [ ] cannot be amended on the date of application submission (issuing a document "Memorandum of Deficiency")	( ) dated

Part 2 Recommendations and Testimonials

Instructions for using the document self-examination form 1. Study the requirements in the relevant pharmaceutical division announcements. complete all items 3. Changes should be clearly displayed in the document. 4. Sort the documents according to the sequence number corresponding to the form. 5. **Self-check responses** are as follows: - Answer **'Yes'** or **'Yes'** or ÿ Means self-checked and complies with the requirements - Answer **'N/A'** or **'Not applicable'.**

When checked, it is found that the requirements indicate that this document is not required. - Answer **'Refer...'** or **'Refer.. .'** Specify the request number or the number + date received Related Note** Leave blank. because the applicant did not check by himself The staff will return the request, so if there is any doubt about the requirements or document preparation Please ask staff **

Applicant/Attorney (name-surname) .... On behalf of (company/ agency) ....

Tel ……..……Fax:……..……..……..……. ……E-mail: ……..

I certify that I have studied and prepared documents according to the requirements of FDA, along with preparing all documents, all items, complete Items Sorted by document list and checked by yourself according to the table below.

sign …… (Applicant/ Attorney) Date.....

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Part 3 Checklist of documents

Clause	checklist	results examine by yourself	Results of inspection by Officer 1st time	Results of inspection by Officer 2nd time	note
*	Acknowledge that you cannot submit an application to change the licensee, drug list or quantity, but cancel the original license and submit an application. reauthorize				
**	Acknowledgment that 1 request can request to change only 1 main issue, such as in the case of requesting to extend the shelf life of a drug (it is change in quality and result in a new expiration date labeling) to be submitted in 1 request, etc.				
*** All copies of documents must be certified as true copies.					
1	**data recording device** (in case of submitting a paper form)				
	1.1 Copy of all submitted documents (MS word 1.2 Excel file . PDF file)				
	for Logistic system				
2	**2.1 Request for amendment of items related to permission according to the form Nov. 1 / Nov. 8 (research)** ☐ e-sub paper ☐				
	1) The information of the authorized person submitting the request is the same as that of the authorized person.				
	2) Express your wish				
	3) Research project information (name, code, TFDA (approved date since Oct. 2016, except for expanding the scope of BE, the PorPorPhor. will not know)				
	4) Specify the main items to be corrected, from, to, and why.				
	5) Are there any changes related to the main issues? If so, specify from, is and why.				
	6) Identify documentary evidence				
	7) Measures to prevent risks and testimonials, such as in case of changes that may pose a risk to the researcher or subject. or in case of request changes due to mistakes In case of requesting drug use across research institutes, must Ensure that evidence is kept complete accounting and can be checked or in the event of a change that may pose a risk to the research or volunteer etc.				
	8) Signed by authorized persons - business operators - top executives at department level and above.				
	2.2 Orders for the assignment of officials In the case where the top executives of ministries, departments in charge of preventing and treating diseases, the Thai Red Cross Society or organizations Pharmacy has been assigned to act on behalf of the duties related to Bringing or ordering drugs into the Kingdom				
3 power of attorney (in case of submitting a paper form)					
	1) Power of attorney (submit request, clarify, amend, receive documents)				
	2) A copy of the attorney's ID card/passport				
	3) A copy of the authorized person's ID card				

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Clause	checklist	results examine by myself	Results of inspection by Officer		note
			1st time	2nd time	
	4) stamp duty 30 baht per 1 attorney				
4	**Copies of relevant licenses 7**				
	1) complete as specified in the request for amendment				
	(add list of documents as appropriate ready to check by yourself)				
5					
6					
7					
8					
9					
10					

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Appendix 18

Request to amend the list of permissions

according to the Nor.Yor.Mor.1 / Por.Yor.8 forms for human research studies

Receipt No.....

date.....

Request recipient.....

4. I ----------

position ----------

on behalf of

[ ] Ministry ---------- [ ] Department ----------

[ ] Thai Red Cross Society [ ] Government Pharmaceutical Organization

[ ] Licensee to manufacture drugs ---------- license number ----------

Name [ ] Licensee to bring or order drugs at the place Name ---------- license number ----------

5. I would like to request an amendment to the list of permission according to form [ ] Nor Yor M. 1,

receipt number [ ] Por ----------

Yor. 8 for human research studies, receipt number 6 for ----------

the project. Name research (Thai language) ----------

---

research project code ---------- and TFDA CT no. ----------

7. Items to be amended (Choose 1 main item)

[ ] Information in the license, **except** licensee information, drug list and quantity

[ ] drug label

[ ] Drug accompanying documents

[ ] Researcher handbook

[ ] Volunteer introduction document

[ ] Summary of the research project

[ ] Details of the research project

[ ] Quality control and drug production documents

[ ] Other (specify) ----------

from ----------

is ----------

due to ----------

and [ ] does not have [ ] there are changes related to the above main items, namely ----------

from ----------

is ----------

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due to ----------

8. Evidence documents

[ ] A copy of the license according to Form Nor.Mor.1 / Por.Por.8 for human research studies.

[ ] drug label

[ ] Drug accompanying documents

[ ] Researcher handbook

[ ] Volunteer introduction document

[ ] Summary of the research project

[ ] Details of the research project

[ ] Evidence of approval from the Ethics Review Committee on human subjects accepted by the FDA

[ ] Others include ----------

---

9. Measures to prevent risks and testimonials (if applicable) ----------

---

sign .... Applicant

(.....)

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Appendix 19

Example of a notice for acknowledgment

Company / department header

date..... ...

Subject: Notification of importing or ordering drugs into the Kingdom for research purposes To:

Director of the Drug Division

Referring to Permits for importing or ordering drugs into the Kingdom for research purposes Receiving

number …… **Attachments (1 set)**

as follows: No. 1 A copy of the license to import or order drugs into the kingdom for research purposes. Receiving

number at …… No. 2 ...(specify)....

...

Number... The file storage device is the same as all documents submitted this time. As

permitted by the Food and Drug Administration.....<name of the company/agency>.....take or to order drugs into the Kingdom for research purposes (Form Nor Yor. M. 1), receipt number at ..... Date received..... For the research project name.....<Thai name>..... ....

Research project code..... TFDA CT no. ..... (if any) that

I would like to notify the Food and Drug Administration of changes made to

Approved/certified by the Research Ethics Committee that the Food and Drug Administration has accepted (Enclosure....) with the following items:

1. <~~Specify what has changed, what was before, what has changed, reasons and preventive measures~~. risk>.....

2. <~~Specify what has changed, what was originally, what has changed, reasons and preventive measures~~. risk>.....

Please be informed accordingly.

Yours sincerely

.....

(.....)

position ....

note: *Signed by the authorized person in accordance with clause 1.1 and filled in factually correct statement.*

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Appendix 20

Form for a summary of the termination/termination of the research project

Company / department header

date..... ...

Subject Summary of termination/termination of the research

project **To:** Director of the Drug

Division **Reference:** License to import or order drugs into the kingdom for research purposes Receiving number

…… **Attachments* (1 set) as follows:**

No. 1 Permit to import or order drugs into the kingdom for research purposes. Receipt No.…… (Real one)

...

Number... The file recording device that is the same as all documents submitted this time.

with (name of company/organization) .... licensee to bring or to order drugs into the kingdom for research purposes In the research project name..... ..... Research project code..... TFDA CT no. ..... (if any) The research project has now been terminated/terminated. due to*…….. The information is summarized as

follows: (1) Project

commencement date ……..Termination date/project termination…Total duration ……. (2) Total research sites in Thailand are…….. (3) The number of subjects who received the drug ……persons (4) The number of subjects separated by research sites as shown

in the table below.

list of research sites	Number of volunteers (people)				
	follow target	screening	participating TRUE	who participated in the research completed as scheduled	leaving the research early
1.					
2.					
3.					
N					

(5) Procedures for Volunteer Tracking In case of termination of the research project due to the safety of research drugs as detailed in the enclosed number..... (6) There is a deviation from the

research proposal that has not been disclosed in the research project progress report form. according to the details in the enclosed number.....

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(7) There is an application for permission. according to Nor.Mor.1 form for the above research project ---------- times, details are as follows:

• pick-up number ---------- Date received ..... Number of requests for import

---

research drug name ---------- Actual amount imported

• pick-up number ---------- date of receipt ---------- Number of requests for import

---

(Additional documents may be attached if there are multiple items)

Including a list of all drugs, the list is as follows: ----------

Investigational drug ---------- Total amount 1. ---------- remaining ----------

name 2. Investigational drug name Total amount (8) Actions for remaining or ---------- remaining ----------

expired research drug with attached evidence

Please be informed accordingly.

Yours sincerely

.....**

(.....)

position ....

note: ** State the reason for terminating/ terminating the research.*

***Signed by the authorized person in accordance with the terms in clause 1.1 and fill in the correct statement according to the facts*

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Appendix 21

Criteria and Method for Reporting Adverse Reactions from Drugs Investigated in Clinical Research

ÿ. definition of term

Definitions of terms other than this list Refer to the ICH Good Clinical Practice book.
Guideline in Thai version published by the Food and Drug Administration

ÿ.ÿ Adverse Drug Reaction (ADR) means

ÿ.ÿ.ÿ Adverse Reactions from a New Investigational Drug or Investigational Drug for New Indication means all adverse and potentially dangerous reactions at any dose. The term “drug-induced” means that, at least, it is reasonably possible to explain that an adverse reaction is a drug-induced effect. Studies that are not irrelevant cannot be ruled out.

1.1.2 Adverse reaction from a commercial drug means any symptom that is dangerous.
or
to modify the physiological functions of the body

1.2 Unexpected Adverse Drug Reaction means an adverse reaction whose nature or severity is not consistent with the relevant product information (e.g. information In the investigator's handbook for research drugs that have not yet been registered. Drug accompanying document or summary drug information that has been registered with the drug formula)

1.3 Serious Adverse Event (SAE) or adverse event
Serious Adverse Drug Reaction means any medical adverse event that occurs upon administration of any dose causing

(1) died

(2) endangering life

(3) having to stay in the hospital for treatment or having to stay in the hospital longer

(4) a significant permanent disability/disability;
or (5) a congenital disability/deformity.

1.4 Annual Safety Data Cut-off Date means
The annual due date of the security data used for the annual security report.

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ÿ. **Reporting Adverse Reactions Occurring During Expedited Clinical Trials**

Reporting)

Those who are allowed to import or order drugs into the kingdom for research purposes/ those who are licensed to produce drugs An example of applying for a formula registration (Form Por Yor. 8) for research studies in humans is responsible for monitoring Safety precautions about research drugs and report to the Food and Drug Administration, with the following requirements:

2.1 **Things to be reported urgently :** 2.1.1

Unexpected serious adverse drug reactions Found in Thailand, which was born from research drug Or that has been reported from other regulatory agencies or publications.

Risks of Investigational Drugs change the way the drug is administered or change the research as a whole, for example

(1) An unexpected serious adverse reaction or used to treat life-threatening diseases; (3) important new information about safety from animal studies, such as

cancer

2.2 **Timelines for Reporting** 2.2.1

Unexpected Serious Adverse Drug Reactions Causing Death or Danger life threatening Must report within 7 days after the authorized person first receives the information. An additional report must be submitted within the next 8 days. Periodic reports should be submitted if additional information is available. life threatening Reports

must be submitted within 15 days after the authorized person first receives the information. Reports must be submitted periodically if additional information is available. research is over The report must be submitted within 15 days after the authorized person receives the information

for the first time. period if there is any further information.

2.3 Urgent reporting methods

2.3.1 Individual reports shall be submitted through the information system of the Security Surveillance Center. health product safety **(http://thaihpvc.fda.moph.go.th)** Except in the event that the system is unavailable or crashes, submit a document report to the New Drugs and Drug Research Promotion Group, Drug Division, Office of the National Drug Administration. food and medicine

2.3.2 Other reports Make a book with information such as a summary of the problem. Risk assessment and related details Submit a group of new drugs and promote drug research, Drug Division, Food and Drug Administration and medicine

2.3.3 Individual reporting information Must consist of at least the following information: (1) Information

that identifies the volunteer such as volunteer ID

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(2) drugs used in research

(3) adverse symptoms or Results suspected to be related to medication which can indicate that it is

Serious and unexpected events

(4) source of traceable reports

(5) research project code or research project name;

(6) Reporting number, such as the report number assigned by the sponsor.

2.3.4 Reporting of research cases where treatment is concealed

Submit a report that reveals the subject's treatment code. In the event that the code cannot be disclosed

treatment of that volunteer Submit a report in which the treatment code has not been disclosed and a report in which the treatment code has not been disclosed.

of subjects later, except in the case where the Office of the Committee deems it appropriate to open the treatment code immediately.

Licensed treatment codes must be disclosed to the Food and Drug Administration as soon as possible.

3. Annual Safety Report and End of

Study Safety Report)

Those who are allowed to import or order drugs into the kingdom for research purposes/ those who are allowed to produce drug samples

To apply for registration of a medicinal formula (Form Por Yor. 8) for research studies in humans. is responsible for surveillance

safety concerning research drugs and annual safety data reports and when the research ended by

Gather information from both domestic and foreign countries. Submit new drug groups and promote drug research, Drug Division, Office

Food and Drug Administration with the following requirements

ÿ.ÿ Reports should be made using the following form: 3.1.1

Safety statement for subjects in the annual trial or at the end of the trial. 3.1.2 Serious adverse drug reactions list

Adverse Drug Reactions)

for each volunteer

3.1.3 Table summarizing the number of serious adverse drug reactions reported

Drug Reaction) separated by terminology (symptoms and diagnosis)

3.2 Report schedule and how to report

3.2.1 Safety report at the end of the trial Must be reported within 6 months after the date of the research.

End, submit a document report to the New Drugs and Drug Research Promotion Division, Drug Division, Office of the Committee.

food and medicine

3.2.2 Annual safety report must be reported within 3 months from the date of intersection of

Annual Safety Data Cut-off Date: Submit a document report to the drug group.

New and Promotion of Drug Research, Drug Division, Food and Drug Administration

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annual safety report book or at the end of the research

Written at (name of department/company, address, telephone number)

date ----------

Subject: Clarification of the safety of subjects in the annual trial/at the end of the trial

Dear Head of New Medicine and Drug Research Promotion Group

Enclosure 1. List of serious adverse drug reactions for each subject.

2. Table summarizing the total number of serious adverse drug reactions reported by terminology.

According to the agency/ ----------

company As a person who is allowed to [ ] bring or order drugs for research (Nor. Yor. 1) [ ] to produce sample drugs (Por. Yor. 8) for human research studies

research project name ----------

---

research project code ---------- TFDA CT no. ---------- (if any)

There is a list of No. Yor. Mor. 1 permitted as follows:

1. No. dated ---------- ----------
2. ----------

have collected and analyzing the safety data and adverse drug reaction reports of the trial [ ] annually or [ ] at the end of the trial.

which consists of information between date and date, would like to clarify and summarize ----------

important issues as the following topics

1. **Security analysis (emphasis on emerging issues)**

---

2. **Benefit-Risk Assessment (emphasis on impact assessment on volunteers/volunteers)**

---

3. **risk management measures**

Please be informed accordingly. If you have any questions or suggestions (Department/Company) ----------

Willing to cooperate fully

sign ----------

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List of serious adverse drug reactions that occurred for each volunteer.

(Line Listing of All Suspected Serious Adverse Drug Reactions)

Reporting Period consists of

[ ] Annual (Annual)

[ ] End of research Study)

data between dates ----------

to ----------

Number of reported adverse reactions

(Numbers of Reports) ----------

Research Project Name (Protocol Name)

Research Project Code (Protocol Code No.) ..... TFDA CT no. .....(if any)

code volunteer (Subject Identification)	reference number (Case Reference No.)	country (Country)	age (Age)	sex (Sex)	Dosage per day (Daily Dose)	birth date Symptoms (Date of Onset)	the date the drug was received (Dates of Treatment)	Adverse reactions wish Reaction)	results per volunteer (Patient's Outcome)	mark cause ts)	code opening result treatment information (Unblinding Results)

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The table summarizes the total number of serious adverse drug reactions reported by terminology (symptoms and diagnosis).

(Aggregate Summary Tabulation of All Serious Adverse Drug Reactions)

Reporting Period		Research Project Name (Protocol Name)
[ ] Annual (Annual)	Contains data between dates ---------- to ----------	----------
[ ] End research (End of Study)		
number of adverse reactions reported (Numbers of Reports) ----------		Research Project Code (Protocol Code No.) .... TFDA CT no. .....(if any)

Number of reports by terms (signs, symptoms and diagnoses) for the trial

Body System/Terminology of Adverse Effects (Body system / ADR term)	***research drug 1* *(Study Drug 1)***	***research drug 2* *(Study Drug 2)***	***Research drug ...* *(Study Drug ...)***	***Research drug N* *(Study Drug N)***	**placebo (Placebo)**	**medicine that conceals the cure (Blinded)**
CNS						
*Hallucinations**	*2*	*2*	*2*	*2*	*2*	*0*
*Confusion**	*1*	*1*	*1*	*1*	*1*	*0*
.....	.....	.....	.....	.....	.....	.....
Sub-total	*3*	*3*	*3*	*3*	*3*	*0*
CV						
.....						
Sub-total						

** Indicates an example of a serious adverse drug reaction.*

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