Includes forms from

Documents attached to the Drug Division's announcement regarding
Details of regulations regarding bringing or ordering drugs into the Kingdom
for clinical research
Dated the 7th August 2023

** for correct display May download fonts TH SarabunPSK
to use in your MS Word **

Appendix 2

N.Y.M.1 form _

Receipt number.....
date.....
Signed.....Recipient of request

Request for permission to import or order drugs into the Kingdom for research purposes

---

Type of ☐modern medicine

☐traditional medicine

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

position .....

On behalf of ☐ministries .....☐, bureaus, and .....

.....☐departments.....

☐ Thai Red Cross ☐ Government Pharmaceutical Organization

☐Drug manufacturing licensee name .....license number.

.....

☐The licensee brings or orders medicine at the place named, ...

.....license number. .....

Address number.....alley/alley .....road.....

.....

Village, ...sub-district/subdistrict, ...district/area.....

.....

Province .....Telephone.....fax.....

.....

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

2. Research project name

(English).....

.....

(Thai language) (if any).....

.....

.....

3. Research project code (if any) .....
4. Research study location.....

.....

5. Name of medicine

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

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

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

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

(*In case there are additional details Please attach additional documents with the same format. which has a number of.....pages*)

6. The evidence has been attached as follows.
    (1) Drug labels for every package size *(Thai language) or English)*
    (2) Medicine documentation (for medicines that have already been registered on the formula)
    (3) Investigator 's Brochure (for drugs that are not yet registered)
    (4) Volunteer Information Sheet (Thai language)
    (5) Summary of research project (Thai language)
    (6) *Complete research project details (Thai language) or English)*
    (7) *Pharmaceutical quality control and production documents*
    (8) *Approval document for research from the Human Research Ethics Committee (Institutional Review Board: IRB or Independent Ethics Committee: IEC) at the Food and Drug Administration.* accept
7. Details of the medicine

No.	Drug name or drug code	Important medicines (Active Ingredients)	Quantity per unit
1			
2			
3			
4			

(*In case there are additional details Please attach additional documents with the same format. which has a number of.....pages*)

(Signature) .....Applicant

(.....)

Note : Put a checkmark ✓into the box ☐next to the desired message.

Appendix 3

Summary of research project (Thai language)

(Updated 7 Aug. 2023)

TFDA CT no.	
Date of receipt	

We hereby certify that the information about the research project or the summary of the research project (in Thai) as shown in the table below is true.

By this document

[..] This is the first time that information on research projects has been provided as of .....

[..] It is considered an update of research project information specified as of ..... (with updated information displayed)

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

sign ..... Person entitled to submit the request/attorney

(..... ....) Script

Date of certification..... ....

Summary of research project (Thai language)			
1.	Name of research project in Thai		
2.	Name of research project in English		
3.	The project code, which is the code set by the research sponsor (sponsor), should be the same across all research sites of the same protocol.		
4.	Project abbreviation or other name	[..] Includes : .... [..] do not have	
5.	IND number of the US FDA	[..] Includes : .... [..] do not have	

Summary of research project (Thai language)			
6.	Research registration (Clinical Trials Registry) (may register with a Thai or foreign registry) More than one is fine.)	*(Please specify the Registry name and URL such as Thai Clinical Trial Registry(http://www.clinicaltrials.in.th/), ClinicalTrials.gov, etc. along with the registration number .)*	
7.	Type of research project (1-4 defined according to ICH-E8 'General Consideration for Clinical Trials')	Phase : [..] 1 (First research on people? [..] Yes [..] No) [..] 2 [..] 3 [..] 4 [..] Biological balance	
8.	Types of research support	[..] Research projects initiated by pharmaceutical companies. [..] Research projects initiated by the researchers themselves.	
9.	Research country	[..] Only in Thailand [..] Research in many countries	
10.	Total number of institutions participating in research around the world		
11.	Total number of volunteers worldwide according to plan		
12.	Number of institutions participating in research in Thailand according to the plan		
13.	Information about each research location in Thailand		
	Name of research facility	Number of volunteers at each research site	Name of principal investigator, address, contact telephone number, email.
(1)			Name of principal investigator address phone. Email
(2)	*Add/delete rows as appropriate.*		
14.	Research sponsors in Thailand (Thai Sponsor)	Organization name address phone. Email / Website	
15.	Research sponsors abroad (Foreign Sponsor)	Organization name address phone. Email / Website	

Summary of research project (Thai language)		
16.	Companies or agencies that oversee research (Monitor)	[ ] Is the applicant [ ] Not the applicant Organization name address phone. Email / Website
17.	Companies or agencies that manage research projects (Project Management)	[ ] Is the applicant [ ] Not the applicant Organization name address phone. Email / Website
18.	Companies or agencies that manage data (Data Management)	[ ] Is the applicant [ ] Not the applicant Organization name address phone. Email / Website
19.	Clinical Laboratory _	[ ] Use the clinical laboratories of each research site. [ ] Use clinical laboratories outside research sites in the country/abroad, including: 1. Organization name address phone. Email / Website 2. Organization name address phone. Email / Website
20.	List of drugs used in the project (Specify all drugs used in the project, including investigational drugs, comparator drugs/placebos and medicines used together regardless of whether permission is requested in this request or not)	

Generic name, strength, dosage form	Trade name	Another name	Dosage given and Washout Period (if any)	Choose only 1 item

Summary of research project (Thai language)					
(1)	*FDAmycin 10 mg.*	-	*SOS-001*	*20 mg every 12 hrs.*	[/] Research medicine [..] comparative medicine [..] Medicines used together
(2)	*Placebo*	-	-	*2 tablets every 12 hours.*	[..] Research medicine [/] Comparative medicine [..] Medicines used together
(3)	*Paracetamol 500 mg.*	*TYLENOL*	*acetaminophen*	*500 mg. Every 6 hrs.*	[..] Research medicine [..] comparative medicine [/] Medicines used together
(4)	*Add/delete rows as appropriate.*				

21.	Type of main research drug of the project	You can choose 1 item. [ ] Vaccines [ ] Vaccines for animals [ ] Biological medicines [ ] Biological medicines for animals [ ] Chemical drugs [ ] Chemical drugs for animals
22.	Research start date in Thailand (approximate)	
23.	End date of research in Thailand (approximate)	
24.	How to find volunteers	[..] Post an advertisement. [..] verbal invitation [..] Others, please explain..... ....
25.	financial support	Please specify all documents showing evidence. [..] Research outline (please specify document name, version , date page clause) [..] Information document for volunteers (please specify document name, version, date page clause) [..] Other, please specify and attach a copy of the document.

Summary of research project (Thai language)		
26.	Evidence of insurance or compensation in the event of illness, injury, disability or death of the volunteer. As a result of clinical research	Please specify all documents showing evidence. [..] insurance [..] Information document for volunteers (please specify document name, version, date page clause) [..] Other, please specify and attach a copy of the document.

Note : Please check mark✓ in [ ] or add text that matches the facts.

Appendix 4

Certification of compliance with the 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 take or prescribe medicine. For research (form N.Y.M.1) for research project name (Thai language) ..

....

....

.....

Research project code ....to be carried out in a research facility and under the supervision of the Human Research Ethics Committee accepted by the Food and Drug Administration as follows:

at	Research location (name and address)	Name of the Human Research Ethics Committee recognized by the Food and Drug Administration. (Please provide full name)	Consideration Result Status	
			wait	Approved date
1.	(You can increase or decrease rows according to the number of research locations)		[.]	[.] .....
2.			[.]	[.] .....
3.			[.]	[.] .....

I promise that

1. Acknowledge and will comply with the terms and conditions specified in Announcement from the Food and Drug Administration Subject: Regulations regarding the importation or ordering of drugs into the Kingdom for clinical research. and announcement of related drug divisions
2. Will comply with the Drug Act B.E. 2510 and related regulations.
3. Relevant documents will be revised according to the opinions of the Food and Drug Administration and the Human Research Ethics Committee that the Food and Drug Administration accepts. and submit the results of the consideration of the committee to consider the ethics of human research that corresponds to the research sites listed in the table above as soon as possible. Along with attaching all updated documents to the Food and Drug Administration, a mark will be displayed on the updated text or clarification of the improvement in detail and clearly.
4. However, I and those involved will not begin the clinical research process at the said research site. Until approval from the Human Research Ethics Committee is accepted by the Food and Drug Administration.

I will abide by the assurances given in every respect. If I do not comply in any case or the documents submitted are false. I agree that the Food and Drug Administration will cancel my application/license and I may be prosecuted for making false statements to officials or other offenses according to relevant laws.

Therefore, sign your name as important to the officials.

sign .... certifying person

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

Business operators or top executives of the Thai Red Cross Society/R.O.P./ministries and departments in the duty of disease prevention and treatment.

Date of certification .....

Note : Please check mark.✓ in [ ] or fill in the text that matches the facts.

Appendix 5

Certification of compliance with the terms and conditions regarding importing or ordering drugs into the Kingdom for clinical research For the principal researcher

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

Research project code .... which has the right to submit an application for permission to take or prescribe medicines For research (Form N.Y.M.1) in the name of .... has submitted a request related to the said research project to the Food and Drug Administration.

I promise that

1. Will cooperate with those eligible to submit applications. In complying with the terms and conditions specified in Announcement from the Food and Drug Administration Subject: Regulations regarding the importation or ordering of drugs into the Kingdom for clinical research. and announcement of related drug divisions
2. Clinical research will be conducted in accordance with Good Clinical Research Practice (GCP) guidelines.
3. Drugs will be used only in research according to the research project of the above research project that has been approved by the Secretary-General of the Food and Drug Administration.
4. Documents related to the above research project will be revised according to the opinions of the Food and Drug Administration and the Human Research Ethics Committee accepted by the Food and Drug Administration. and send the results of the consideration of the committee to consider the ethics of human research to those eligible to submit the above request so that they can submit it to the Food and Drug Administration according to the regulations.
5. **Documents related to the revised research project will be used in research only if they have received approval from the Human Research Ethics Committee at the Food and Drug Administration.**
6. **It will facilitate the officials of the Food and Drug Administration in inspecting research (Inspection) both before and after research. During research and after the research ends or after the termination of the research project.**
7. The clinical research process of the above research project will not be initiated at the research site under my responsibility. Until approval from the Human Research Ethics Committee is accepted by the Food and Drug Administration. and has been permitted to import or order drugs into the Kingdom for research purposes **only**

I will abide by the assurances given in every respect. If I do not comply in any case The Food and Drug Administration may issue an order suspending research or suspending use of a drug. As appropriate to the case

Therefore, sign your name as important to the officials.

sign .... certifying person

(..... .....) (Principal researcher)

Research location.....

.....

Date of certification.....

.....

Note : Please check mark.✓ in [ ] or fill in the text that matches the facts.

Appendix 6

Form requesting relaxation of drug labeling requirements for specific cases

Please study the details of the labeling requirements for every package size and the conditions for requesting relaxation of drug labeling requirements in specific cases in the document attached to the announcement of the Department of Drugs on the details of the requirements for importing or ordering drugs into the Kingdom for clinical research or Subject: Details of regulations regarding the production of modern drug samples for clinical research, latest edition.

1. General information

1.1. Information about those eligible to submit an application	
Applicant's name	
on behalf of	
1.2. Clinical research project information	
Name of research project (Thai language)	
Research project code	

2. The details of the request for relief are specific cases. *(According to the terms and conditions detailed in the document attached to the Department of Drug Administration's announcement)*

2.1. Name of medicine as specified in the request	
2.1.1. An explanation of what you want to request for a waiver of.	
2.1.2. Reason of necessity	
2.1.3. Attach documents for consideration as follows: 1. 2.	

Note: The same table may be added for each drug entry.

3. testimonial

I will consider the rights, safety and well-being of my volunteers. As well as reliable clinical research results, it is important and will direct those involved to carry out the details that have been reported to the Food and Drug Administration.

sign .... (Applicant requesting a deferment) *

(..... .....)

position ... .

date ....

* Applicants requesting a waiver are according to those eligible to apply for permission from N.Y.M.1 or Por.Yor.8.

Appendix 7

Form summarizing evidence of quality control documents and drug production separated by drug

We certify that the information in the form summarizes evidence of quality control documents and drug production separated by drug. As shown in the table below is true by this document.

[..] This is the first time that information on drugs has been provided as of .....

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

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

sign ..... Person entitled to submit the request/attorney

(..... ....) Script

Date of certification..... ....

[ ] research drug Item..... **[ ] comparative medicine** Item..... **[ ] Concomitant medicine** Item.....	
1. Trade name of Drug Product	
2. Drug Substance 's generic name or alternative name (e.g. code)	
3. Dosage form and strength	
4. Treatment group	
5. Type of medicine [ ] **Type 1** A new investigational drug that has not been previously studied in clinical trials. [ ] **Type 2** A new investigational drug that is currently in Phase 1, 2, or 3 clinical trials. [ ] **Type 3** Medicines that have been registered in the pharmacopoeia (Thailand or abroad) but is conducting clinical research to study new indications, new methods of drug administration, or new types of drug forms, etc. [ ] **Category 4** drugs that are registered in the drug formula (Thai or foreign) but used in this research project as research medicine. comparative medicine or drugs used in conjunction with the indications and methods of drug administration or a form of medicine that has been registered	
6. Manufacturer of drugs to be imported (name, address, country)	
7. Sponsor (name, address, country)	
8. Which country will the production version of the medicine be imported from?	

[ ] research drug Item..... **[ ] comparative medicine** Item..... **[ ] Concomitant medicine** Item.....	
9. Status of registration of drug formulas in the country according to Section 8	
10. Evidence of quality control documents and drug production attached *** Select one of the four options whose manufacturer matches the one confirmed in Item 6 and also matches the EXCEL file for the Logistics system.**	[ ] NCE [ ] Reference to registration of drug formulas in Thailand (Registration certificate number..... .....) [ ] CPP / CFS with GMP certification and sales confirmation [ ] Other evidence of registration from the drug regulatory agency

note 1) Add the same table for each medicine. 2) Please check the box.✓ In [ ] 3) Fill in the text that matches the facts.

Appendix 8

Evidence of drug quality information NCE (New Chemical Entity)

attached NCE (New Chemical Entity) evidence of drug quality information is true. This document

[..] This is the first time that information on drugs has been provided as of .....

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

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

sign ..... Person entitled to submit the request/attorney

(..... ....) Script

Date of certification..... ....

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

Item Topic		Minimum required topics For research term		
		1 , BE	2	3 , 4
S.2.1 Manufacturer(s) (name, manufacturer)		✓	✓	✓
-	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	✓	✓	✓
S.2.2 Description of Manufacturing Process and Process Controls (name, manufacturer)		✓	✓	✓
-	Flow diagram of the synthetic process(es)	✓	✓	✓
-	Narrative description of the manufacturing process(es)	-	✓	✓
S.2.3 Control of Materials (name, manufacturer)		✓	✓	✓
-	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 (eg, ruminant origin), provide an attestation (with supporting documentation, if applicable) confirming that the material is free of BSE/TSE agents	✓	✓	✓
-	Information on starting materials	-	✓	✓
S.2.4 Controls of Critical Steps and Intermediates (name, manufacturer)		-	-	✓
-	Summary of the controls performed at critical steps of the manufacturing process and on intermediates	-	-	✓
S.3 Characterisation (name, manufacturer)		✓	✓	✓
S.3.1 Elucidation of Structure and other Characteristics (name, manufacturer)		✓	✓	✓
-	List of studies performed (eg, IR, UV, NMR, MS, elemental analysis) and summary of the interpretation of evidence of structure	✓	✓	✓
-	Discussion on the potential for isomerism and identification of stereochemistry (eg, geometric isomerism, number of chiral centers and configurations)	✓	✓	✓
-	Summary of studies performed to identify potential polymorphic forms (including solvates), if available	✓	✓	✓
-	Summary of studies performed to identify the particle size distribution of the drug substance, if available	✓	✓	✓
-	Other characteristics	✓	✓	✓
S.3.2 Impurities (name, manufacturer)		✓	✓	✓
-	Identification of potential and actual impurities arising from the synthesis, manufacture and/or degradation	✓	✓	✓
	List of drug-related impurities (eg, starting materials, by-products, intermediates, chiral impurities, degradation products, metabolites), including chemical name and origin	✓	✓	✓

<table>
<tr><th colspan="2">Item Topic</th><th>Minimum required topics For research term
1 , BE</th><th>2</th><th>3 , 4</th></tr>
<tr><td></td><td><table>
<tr><td>Drug-related Impurity
(chemical name or descriptor)</td><td>Structure</td><td>Origin</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td><td></td><td></td><td></td></tr>
<tr><td></td><td>List of process-related impurities (eg, residual solvents, reagents, catalysts), including compound name and step used in synthesis</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Actual levels of impurities (eg, drug-related and process-related) found in batches to be used in this clinical trial
<table>
<tr><td rowspan="2">Impurity
(drug -related and process-related)</td><td rowspan="2">Acceptance Criteria</td><td colspan="3">Results
(include batch number and use)
(eg, clinical)</td></tr>
<tr><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>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.4 Control of the Drug Substance (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.4.1 Specification (name, manufacturer)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Specification for the drug substance
<table>
<tr><td>Test</td><td>Acceptance Criteria</td><td>Analytical Procedure
(Type and Source)</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.4.2 Analytical Procedures (name, manufacturer)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of the analytical procedures (eg, suitability, key method parameters, conditions)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.4.3 Validation of Analytical Procedures (name, manufacturer)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Tabulated summary of the validation information (eg, system suitability testing, validation parameters and results)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.4.4 Batch Analyzes (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Description of the batches to be used in this clinical trial
<table>
<tr><td>Batch Number</td><td>Batch Size</td><td>Date of Manufacture and Site of Production</td><td>Use (eg, clinical)</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
</table></td><td>✓</td><td>✓</td><td>✓</td></tr>
</table>

Item Topic		Minimum required topics For research term		
		1 , BE	2	3 , 4
-	Summary of results for the batches to be used in this clinical trial (should include tests, types of analytical procedures (eg, HPLC, GC), and actual results)	✓	✓	✓
S.4.5 Justification of Specification (name, manufacturer)		-	✓	✓
-	Justification of the drug substance specification (eg, manufacturing experience, stability, historical batch analysis results, safety considerations)	-	✓	✓
S.6 Container Closure System (name, manufacturer)		✓	✓	✓
-	Description of the container closure system(s) for the storage and shipment of the drug substance	✓	✓	✓
S.7 Stability (name, manufacturer)		✓	✓	✓
S.7.1 Stability Summary and Conclusions (name, manufacturer)		✓	✓	✓
-	Summary of stability studies to support this clinical trial (eg, studies conducted, protocols used, results obtained)	✓	✓	✓
-	Proposed storage conditions for the drug substance	✓	✓	✓
S.7.2 Stability Protocol and Stability Commitment (name, manufacturer)		✓	✓	✓
-	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	✓	✓	✓
S.7.3 Stability Data (name, manufacturer)		✓	✓	✓
-	The actual stability results (ie, raw data) may be found in	✓	✓	✓
-	Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.S.4 (eg, analytical procedures used only for stability studies)	-	✓	✓
DRUG PRODUCT (NAME, DOSAGE FORM)		✓	✓	✓
P.1 Description and Composition of the Drug Product (name, dosage form)		✓	✓	✓
-	Description of the dosage form	✓	✓	✓
-	Composition of the dosage form	✓	✓	✓
	Composition, ie, list of all components of the dosage form, and their amounts on a per unit basis (including overages, if any)	✓	✓	✓

Component and Quality Standard (and Grade, if applicable)	Function	Strength (label claim)			
		Quantity per unit	%	Quantity per unit	%

Item Topic		Minimum required topics For research term		
		1 , BE	2	3 , 4
	Total			
	Composition of all components that are mixtures (eg, colorants, coatings, capsule shells, imprinting inks)	✓	✓	✓
-	Description of accompanying reconstitution diluent(s), if applicable	✓	✓	✓
-	Type of container closure system used for accompanying reconstitution diluent(s), if applicable	✓	✓	✓
-	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)	-	✓	✓
P.2 Pharmaceutical Development (name, dosage form)		✓	✓	✓
-	Discussion on the development of the dosage form, the formulation, manufacturing process, etc	-	✓	✓
-	For sterile, reconstituted products, summary of compatibility studies with diluents/containers	✓	✓	✓
P.3 Manufacture (name, dosage form)		✓	✓	✓
P.3.1 Manufacturer(s) (name, dosage form)		✓	✓	✓
-	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	✓	✓	✓
-	Attestation that the dosage form was manufactured under Good Manufacturing Practices (GMP) conditions	✓	✓	✓
P.3.2 Batch Formula (name, dosage form)		✓	✓	✓
-	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) 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)		✓	✓	✓
-	Flow diagram of the manufacturing process	✓	✓	✓
-	Detailed narrative description of the manufacturing process, including equipment type and working capacity, process parameters	-	✓	✓
-	For sterile products, details and conditions of sterilization and lyophilization	✓	✓	✓

<table>
<tr><th colspan="2" rowspan="2">Item Topic</th><th colspan="3">Minimum required topics For research term</th></tr>
<tr><th>1 , BE</th><th>2</th><th>3 , 4</th></tr>
<tr><td colspan="2">P.4 Control of Excipients (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.4.1 Specifications (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.4.5 Excipients of Human or Animal Origin (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>List of excipients that are of human or animal origin (including country of origin)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of the information (eg, sources, specifications, description of the testing performed, viral safety data) regarding adventitious agents for excipients of human or animal origin</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>For excipients obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (eg, ruminant origin), provide an attestation (with supporting documentation, if applicable) confirming that the material is free of BSE/TSE agents</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.4.6 Novel Excipients (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5 Control of Drug Product (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.1 Specification(s) (name, dosage form)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><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>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.2 Analytical Procedures (name, dosage form)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of the analytical procedures (eg, key method parameters, conditions, suitability)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.3 Validation of Analytical Procedures (name, dosage form)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Tabulated summary of the validation information (eg, system suitability testing, validation parameters and results)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.4 Batch Analyzes (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><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 (eg, clinical)</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>✓</td><td>✓</td><td>✓</td></tr>
</table>

Item Topic		Minimum required topics For research term		
		1 , BE	2	3 , 4
-	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)	✓	✓	✓
P.5.5 Characterisation of Impurities (name, dosage form)		✓	✓	✓
-	Information on the characterization of impurities, not previously provided in S.3.2 (eg, summary of actual and potential degradation products)	✓	✓	✓
P.5.6 Justification of Specification(s) (name, dosage form)		-	✓	✓
-	Justification of the drug product specification (eg, manufacturing experience, stability, historical batch analysis results, safety considerations)	-	✓	✓
P.7 Container Closure System (name, dosage form)		✓	✓	✓
-	Description of the container closure systems, including unit count or fill size,	✓	✓	✓
-	Materials of construction of each primary packaging component	✓	✓	✓
-	For sterile products, details of washing, sterilization and depyrogenation procedures for container closures	✓	✓	✓
P.8 Stability (name, dosage form)		✓	✓	✓
P.8.1 Stability Summary and Conclusions (name, dosage form)		✓	✓	✓
-	Summary of stability studies to support this clinical trial (eg, studies conducted, protocols used, results obtained)	✓	✓	✓
	Description of stability study details	✓	✓	✓

Storage Conditions (°C, % RH, light)	Strength and Batch Number	Batch Size and Date of Manufacture	Container Closure System	Completed (and Proposed) Test Intervals

	Summary and discussion of stability study results	✓	✓	✓
-	Proposed storage conditions and shelf life (and in-use storage conditions and in-use period, if applicable)	✓	✓	✓
P.8.2 Post-approval Stability Protocol and Stability Commitment (name, dosage form)		✓	✓	✓
-	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.	✓	✓	✓
P.8.3 Stability Data (name, dosage form)		✓	✓	✓

Item Topic		Minimum required topics For research term		
		1 , BE	2	3 , 4
-	The actual stability results (ie, raw data) may be found in	✓	✓	✓
-	Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.P.5 (eg, analytical procedures used only for stability studies)	-	✓	✓

ATTACHMENTS

Attachment Number	Subject

Appendix 9

Letter of submission of results for consideration by the Human Research Ethics Committee

Company header

date..... ...

Subject: Requesting results of consideration from the Human Research Ethics Committee (after parallel submission)

Dear Director of the Drug Division

Refer to the license to produce sample medicine (Por.Yor.8) for conducting research studies on humans. Receipt number..... .

Attached items* (1 set) as follows:

1. Copy of license to produce sample medicine (Por.Yor.8) for research in humans, receipt number.....

2. Committee to consider the ethics of human research.....(specify name)..... namely

Number 2.1 Approval or result of consideration from the Human Research Ethics Committee.....(specify name).....

Number 2.2 Volunteer recommendation document..... (edited version)

Number 2.3 ..... (edited version)

3. Committee to consider the ethics of human research.....(specify name)..... namely

Number 3.1 .....

.... File data recording equipment that is the same as all documents submitted this time.

As the Food and Drug Administration allows.....<Licensee>.....to produce drug samples (Pho. 8) for research in humans, receipt number ... . Date of receipt..... For the research project named in Thai..... ....

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

Now, I have received all the results of consideration from the Human Research Ethics Committee. Therefore, we would like to submit the results of the consideration and all related documents and evidence that have been revised according to the opinions of the Food and Drug Administration and the Human Research Ethics Committee.

In this regard, I would like to state that

[ ] Every research location specified in the license. approved

[ ] Some research locations specified in the license Not approved include: 1)..... and 2)..... I would like to notify you of the cancellation of the said research location. and certify that the medicine will not be used at the canceled research site

Please be informed accordingly.

Best regards

....

(..... .....)

position .....

Note: Signed by the authorized person according to the requirements in Section 1.1 and marked Related message page and fill in the correct statements according to the facts

Appendix 10

Sample letter for submitting a progress report

Company header

date..... ...

Subject: Request to submit a progress report of a research project. ..... For the year .....

Dear Director of the Drug Division

Refer to the license to produce sample medicine (Por.Yor.8) for conducting research studies on humans. Receiving number...<specify all requests>...

Attached items* (1 set) as follows:

Number 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.....<company/organization name>.....to produce drug samples (Phor.8) for research in humans, receipt number no. ..... Date of receipt..... For the research project named.....<Thai name>..... .... Research project code.....

TFDA CT no. ..... (if any) as detailed in attachment number 1

Now, I would like to submit a report on the progress of the research project in accordance with the requirements in the relevant announcement of the Food and Drug Administration and attached herewith.

Therefore, I would like to study for your consideration.

Best regards

....

(..... .....)

position .....

Note: Signed by the authorized person according to the requirements in Section 1.1 and fill in the correct information according to the facts.

Appendix 11 (Updated 7 Aug. 2023)

Document self-check form for requesting permission to import or order drugs into the Kingdom for research purposes (Form N.Y.M.1)

number check	
date	
Project ID	
TFDA CT no.	

Part 1 summarizes the results of document inspection. (Officers only)			
Type of research drug (main) [ ] Biological medicine [ ] Animal medicine [ ] Phase 1 investigational drug [ ] Other	**The time of requesting permission of the same project** [ ]	**Quality data type** [ ] CMC (at least 1 drug) [ ] Registration reference (all)	**In the case where CMC has previously received permission Come before or not?** [ ] ever [ ] never
Summary of document inspection results [ ] Receive the request (issue the document "Form notifying the results of the consideration of the request") [ ] cannot be edited in Date of submitting the request (issuance of document " Record of defects ")		**Request Inspector** ( ) dated	

Part 2 : Instructions and steps

!! Please read !!

Instructions for using the self-document submission check form

1. Study the details of the terms and conditions in **the announcement of the Food and Drug Administration and the announcement of the Drug Division. related**
2. Read the instructions and testimonials. and fill in information in Part 3 and Part 4
3. Check yourself by **answering the results of the self-check** as follows.
   - Answer ' **Yes** ' or ' **Yes** ' or ✓ means you have checked yourself and it meets the requirements.
   - Answer **'N/A'** or **' Not applicable '.** Upon inspection, it was found that the regulations stated that this document was not required to be submitted.
   - **Answer ' Reference... ' or 'Refer** ... Specify the request receipt number or the notification receipt number + the relevant receipt date

Part 3 Certification of document preparation

Person with rights /attorney .... in the name

(Agency) ....

Call .... Fax . ...E-mail: ... .

We hereby certify that we have studied and prepared documents according to FDA regulations (including announcements from the Food and Drug Administration and related announcements of the Division of Medicine) and have submitted Form N.Y.M.1 and all other documents. Sort by document list and check it yourself according to the table in section 4

Signed ..... (authorized person /attorney) Date..... ....

Part 4 Document check table

clause	Document list	Results of self-inspection	Results of inspection by officials		note
			# 1	# 2	
*	Signed to certify or certified true and complete copy				
**	This same research project There is only one person applying for permission to be my agency in Thailand. (Only new projects from 1 Oct. 2016)				
1	**About submitting this request (please fill in information)**				
	The time.....of requesting permission for the same project				
	[ ] Submit after all EC approvals or [ ] Parallel waiting for EC results				
	Please specify the main investigational drug used for the study according to the main objective of this research project. It is the item..... which is classified as a type of drug [ ] Biological medicine [ ] Animal medicine [ ] Phase 1 investigational drug [ ] other				
2	**Data recording device** (only paper submission **)**				
	2 .1 File copies of all submitted documents (PDF file)				
	2 .2Data template file				
	3 .3 Manufacturer in the file direct to the manufacturer notified in Form 11.1.				
3	**N.Y.M.1 form** ☐ 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) Name of Thai research project corresponds to EC approval or in the case of parallel submission. To match the research project summary (Thai language)				
	3.2 In the case of submitting a paper form Submit 2 copies with real signatures + fill in information completely.				
	1) Like the prototype form as announced by the Ministry of Public Health.				
	2) Signed by the authorized person With 2 real signatures				
	3) The medicine list corresponds to Template				

clause	Document list	Results of self-inspection	Results of inspection by officials		note
			# 1	# 2	
	3.3 Orders for assigning government officials In the case where the highest executive of a ministry or department in charge of disease prevention and treatment, the Thai Red Cross Society or the Government Pharmaceutical Organization There is an assignment to perform duties related to importing or ordering drugs into the Kingdom.				
4	**Summary of research project (Thai language) According to the form specified by the FDA.** (Fill in information through the system)				
	1) Name of research project in Thai				
	2) Name of research project in English				
	3) Project ID (this should be the same across all research sites of the same protocol)				
	4) Project abbreviation or other name				
	5) IND number of the US FDA				
	6) Clinical Trials Registry				
	7) Type of research project				
	8) Types of research support				
	9) Research country				
	10) Total number of institutions participating in research around the world				
	11) Total number of volunteers worldwide according to plan				
	12) Number of institutions participating in research in Thailand according to plan				
	13) Information about each research location in Thailand				
	14) Research sponsors in Thailand				
	15) Research sponsors abroad				
	16) Companies or agencies that oversee research (Monitor)				
	17) Companies or agencies that manage research projects (Project Management)				
	18) Companies or agencies that manage data (Data Management)				
	19) Clinical laboratory				
	20) List of drugs used in the project (both according to N.Y.M.1 and those procured within the country)				
	21) Type of main research drug of the project				
	22) Research start date in Thailand (approximate)				
	23) End date of research in Thailand (approximate)				
	24) How to find volunteers				
	25) financial support + with attached documents				

clause	Document list	Results of self-inspection	Results of inspection by officials		note
			# 1	# 2	
	26) Evidence of insurance or compensation in the event of illness, injury, disability or death of the volunteer. As a result of clinical research + with attached documents				
5	**Certification of compliance with the terms and conditions for applicants for N.Y.M.1**				
	1) The signatory is the same person who signed the N.Y.M.1 form.				
	2) The research project code corresponds to the research outline.				
	3) EC that FDA accepts				
	4) Complete information				
	5) Contents are as specified.				
6	**Certification of compliance with terms and conditions For the principal researcher**				
	1) The research project code corresponds to the research outline.				
	2) Complete information				
	3) Contents are as specified.				
	4) The principal investigator provided complete certification at all research sites.				
7	**Medicine labels for every package size (Thai or English)** namely 1) Medicine label ..... 2) Medicine label				
	7 .1 All containers and all sizes have the same format as the actual labels.				
	7.2 Use Thai language **except for** drug names / drug codes and research project sponsor information. Can use Thai or English. and the case of drugs administered by medical personnel. Can use Thai or English.				
	7.3 Secondary labels include (at least)				
	(1) Drug name/drug code, strength, form route of administration Unit quantity In the case of concealment of treatment, specify : “placebo or [drug name/drug code] + [dose and strength] ”				
	(2) Research project code or research project name				
	(3) Production model and or code number to indicate components and packaging.				
	(4) Volunteer number or treatment number and appointment number (if relevant)				

clause	Document list	Results of self-inspection	Results of inspection by officials		note
			# 1	# 2	
	(5) Medication methods may be based on documents specifically designed to be explained to volunteers (such as medication records) or personnel who administer medicinal products .				
	(6) name Address and telephone of the Sponsor/CRO/ researcher , unless the volunteer receives an identification card showing these information (with attached documents)				
	(7) Statement “ For clinical research use only ”				
	(8) Drug storage conditions				
	(9) Specify use by date/expiration date/retest date (month/year)				
	(10) The message "Keep out of the reach of children" in Thai, except that the volunteer did not take the medicine home.				
	7.4 Primary label, general case, consists of (at least)				
	(1) Drug name/drug code, strength, form route of administration Unit quantity In the case of concealment of treatment, specify : “placebo or [drug name/drug code] + [dose and strength] ”				
	(2) Research project code or research project name				
	(3) Production model and or code number to indicate components and packaging.				
	(4) Volunteer number or treatment number and appointment number (if relevant)				
	(5) Medication methods may be based on documents specifically designed to be explained to volunteers (such as medication records) or personnel who administer medicinal products .				
	(6) name Address and telephone of the Sponsor/CRO/ researcher , unless the volunteer receives an identification card showing these information (with attached documents)				
	(7) Statement “ For clinical research use only ”				
	(8) Drug storage conditions				
	(9) Specify use by date/expiration date/retest date (month/year)				
	(10) The message "Keep out of the reach of children" in Thai, except that the volunteer did not take the medicine home.				

clause	Document list	Results of self-inspection	Results of inspection by officials		note
			# 1	# 2	
	7.5 Primary labels in the case where the primary packaging is always together with the secondary packaging. Contains (at least)				
	(1) Drug name/drug code, strength, form Dosage route (except oral solids) Quantity unit In the case of concealment of treatment, specify : "placebo or [drug name/drug code] + [dose and strength] "				
	(2) Research project code or research project name				
	(3) Production model and or code number to indicate components and packaging.				
	(4) Volunteer number or treatment number and appointment number (if relevant)				
	(5) name Sponsor/CRO/ Researcher				
	7.6 Primary label in the case of primary packaging Available in blister format or small units with an area of no more than 3 square inches and always in conjunction with secondary packaging, consisting of (at least)				
	(1) Dosage route (except oral solids) Quantity unit In the case of disclosing treatment, specify : drug name/drug code and dosage and strength				
	(2) Research project code or research project name				
	(3) Production model and or code number to indicate components and packaging.				
	(4) Volunteer number or treatment number and appointment number (if relevant)				
	(5) name Sponsor/CRO/ Researcher				
	7.7 In the case of preparing drugs for administration at the research site, new labels must be attached to the packaging where the drugs will be administered. (To be complied with, but not required to be submitted together with the request)				
	(1) The label is appropriate and correct for the purpose.				
	(2) There is an SOP or standard method that complies with GMP.				
	(3) Operated by qualified and trained personnel.				
	(4) There is evidence of practice records. and verification by at least a second person. Under strict control				
	(5) Collect evidence and record documents to support audits.				

clause	Document list	Results of self-inspection	Results of inspection by officials		note
			# 1	# 2	
	7.8 If there is a necessary reason Relaxation may be granted in specific cases. The following				
	☐ Information on drug labels in MRCT is relaxed and may not be changed immediately. When first submitted Pass the inspection and be accepted into the system within 30 April 2021. - Form requesting relaxation of drug labeling requirements for specific cases				
	☐ Relaxation of information on the label that may refer to other documents, such as how to give medicine, reference to medication records, etc. - Form requesting relaxation of drug labeling requirements for specific cases - Documents referenced include:				
	☐ Adding labels after importing drugs into Thailand to comply with regulations [**In the case of labeling at the production site A place that has permission to produce the correct medicine.]** - Form requesting relaxation of drug labeling requirements for specific cases - Labels or label images that have the same format as actual labels - The place where the labeling is carried out is Places that are licensed to produce the correct medicines. Name .... Modern drug production license number..... .... - **or** in the case of necessity Request for a waiver of labeling operations in places that can be controlled in accordance with the conditions instead. 1) Specify **the reason** and 2) Attach **SOP** [Appropriate personnel trained There are procedures, records, and verification by a second person. It is strictly controlled. and complies with GMP]				
8	**Medicine documentation (for medicines that have already been registered on the formula)** namely 6 .1 Medicine documentation ..... 6.2 Medicine documentation				
	Belongs to the registered formula referred to in item 11 *				

clause	Document list	Results of self-inspection	Results of inspection by officials		note
			# 1	# 2	
	If in another language Please translate into Thai/English and certify that the text in other languages matches Thai / English*				
9	**Investigator 's Brochure (for drugs that are not yet registered)**				
	There is evidence that an up-to-date Investigator Handbook document has been submitted to the Ethics Review Committee. (except for parallel filing)				
	Table of contents, summary, introduction				
	Physical, chemical, pharmaceutical properties and formulations				
	Results of studies not conducted on humans (Animal Study)				
	1. Pharmacology				
	2. Pharmacokinetics and transformation processes in experimental animals				
	3. Toxicology				
	Results of human studies (Clinical Study)				
	1. Pharmacokinetics and product transformation processes				
	2. Safety and effectiveness				
	3. Marketing experience				
	Summary of information and recommendations for researchers				
10	**Volunteer Information Sheet (Thai)**				
	1) Contain appropriate language for volunteers*				
	2) EC approval (except for parallel submission)				
	3) Estimated number of volunteers participating in research for the entire project and the number of volunteers at each institution in Thailand (page.....)				
	4) Indicates that the FDA is the research supervisor. IRB/IEC research reviewers and regulatory agencies law Permission will be given to directly inspect the subjects' original medical records. (page.....)				
	5) stated as research				
	6) Aim of the research				
	7) Treatment given and chance to be randomly assigned				
	8) Methods for conducting research and invasiveness of the body				
	9) Volunteer responsibilities				
	10) The part of the research project that is an experiment				

clause	Document list	Results of self-inspection	Results of inspection by officials		note
			# 1	# 2	
	11) Potential risks or inconveniences to volunteers or to the embryo or fetus or who drinks mother's milk.				
	12) Expected benefits In the event that there is none, volunteers must be notified.				
	13) Alternative procedures or treatments				
	14) Compensation and / or treatment that the volunteer will receive				
	15) Payment of remuneration (if any) which is determined on a per-time basis.				
	16) Various expenses (if any)				
	17) State that volunteer participation in research is voluntary. and may refuse to participate or withdraw from the research at any time. without guilt or loss of benefits that volunteers should receive				
	18) It states that the personal information of volunteers will be kept confidential. and will not disclose this information to the public beyond the scope of the law. Even though the research results have been published				
	19) Specify that volunteers or their legal representatives will be informed of new information in a timely manner. This may affect the willingness of volunteers to continue participating in the research.				
	20) Who to contact for further information about the research and the rights of human subjects and the person who will be notified in the event of danger resulting from research.				
	21) Circumstances / reasons that may withdraw subjects from research				
	22) The expected duration of the volunteer's participation in the research.				
11	**Complete research project details (Thai) or English)**				
	1) EC approval (except for parallel submission)				
	2) General information				
	3) Research background information				
	4) Objectives and aims of the research				
	5) research design				
	6) Selection of volunteers and withdrawal of volunteers				
	7) Caring for volunteers				
	8) Effectiveness evaluation				
	9) Safety assessment				

clause	Document list	Results of self-inspection	Results of inspection by officials		note
			# 1	# 2	
	10) statistics				
	11) Direct access to original data and original documents				
	12) Quality control and quality assurance of research				
	13) Ethics related to research				
	14) Data management and record keeping				
	15) Financial support and insurance (if not specified in this document) A separate agreement may be attached) *				
	16) Research publication policy				
	17) More details				
12	**Pharmaceutical quality control and production documents**				
	11.1 Form summarizing evidence of quality control documents and drug production separated by drug list.				
	- As for the certification, fill out the information and sign completely.				
	- Fill in complete information All medicine items that will be requested for N.Y.M.1				
	11.2 Attached evidence of quality control and drug production documents.				
	1) **NCE for Phase** ... .. . **drug**				
	- As for the certification, fill out the information and sign completely.				
	- The manufacturer in the evidence matches the manufacturer reported in Form 11.1.				
	- GMP certificate by government agencies and not yet expired				
	- Drug Substance has complete information according to the specified subtopics.				
	- Drug Product has complete information according to the specified subtopics.				
	2) **Reference to drug registration in Thailand** (Registration certificate number..... .....) for medicine..... Along with attaching a copy				
	- The manufacturer in the evidence matches the manufacturer reported in Form 11.1.				
	3) **Registration of drug formulas abroad** (CPP / CFS / evidence of registration from drug regulatory agencies) of drugs.....				
	- not yet expired				

clause	Document list	Results of self-inspection	Results of inspection by officials		note
			# 1	# 2	
	- The production source in the evidence matches the drug that will be imported for research.				
	- In the case of showing proof of registration from the website of the drug regulatory agency. But the manufacturer identification was not found. In the website/drug insert/label, attach an additional COA .				
13	**Approval document to conduct research from the human research ethics committee. at the Food and Drug Administration accept (of all agencies according to regulations)** **12 .1 Name of organization .....** **12.2 Name of organization .....** **(Except for parallel submissions, they may not be available or may be incomplete.)**				
	1) Thai version*				
	2) The name of the IRB/IEC corresponds to the FDA announcement.				
	3) Research project name				
	4) Researcher's name				
	5) Names of all approved research facilities				
	6) research project documents and related documents, including specifying the version approved by the Human Research Ethics Committee.				
	7) Period approved for research and/or expiration date				
14	**Document for calculating the amount of medication**				
	1) Refer to the number of volunteers as requested by EC .				
	2) Calculate quantities for the entire planned project period.				
	3) In cases where the duration of drug administration is not specified, the exact number of days, months, or years is not specified. To be calculated not more than 4 years.				
15	**power of attorney** (Only in the case of submitting paper)				
	1) Power of attorney (submit a request, clarify, amend, receive documents)				
	2) Copy of the power of attorney's ID card/passport				
	3) Copy of the attorney's ID card				
	4) Stamp duty 30 baht per 1 attorney.				

clause	Document list	Results of self-inspection	Results of inspection by officials		note
			# 1	# 2	
16	**Other (if any)** - Approval documents from the committee or academic subcommittee related to investigational drugs with special supervision, such as AIDS vaccines, etc. -				

Appendix 12

Form for requesting corrections/additional clarifications

for Applicant/attorney :ch I (First name-Last name)..... .... On behalf of..... .... who is the applicant/attorney for the request N.Y.M.1, receipt number …… ... date of receipt …… ..…… ... and have been notified to correct / clarify within …… ....…… Please clarify various issues by submitting the following documents :	Clinical drug research work Date of receipt..... ... recipient..... .....

document number	Document list (Please prepare, certify, and check the documents yourself.)	For the applicant Check it yourself (Answer ✓ means checked, blank = not checked, will be returned)
*	Sign an affidavit or certify that every copy of the document is correct.	
1	Data recording device 1.1 [ ] Copies of all submitted documents (PDF file)	
	1.2 [ ] Excel file for logistics system	
2	Explanation letter	
	(Add a list of documents as appropriate Ready to check by yourself)	

I certify that I have clarified various issues. According to the evaluator's opinion along with submitting 1 set of documents
Complete all items that have been notified for clarification/correction.

sign ..... **(Applicant/attorney)** Dated.....
(..... .....)

Note : Please check mark.✓ in [ ] or fill in the text that matches the facts.

Appendix 13

Letter of submission of results for consideration by the Human Research Ethics Committee

Company / department header

date..... ...

Subject: Requesting results of consideration from the Human Research Ethics Committee (after parallel submission)

learn Director of the Drug Division

Refer to the license to bring or order drugs into the Kingdom for research, receipt number ... .

Attached items* (1 set) as follows:

1. Copy of license to import or order drugs into the Kingdom for research, receipt number .....
2. Committee to consider the ethics of human research.....(specify name)..... namely

Number 2.1 Approval or result of consideration from the Human Research Ethics Committee.....(specify name).....

Number 2.2 Volunteer recommendation document..... (edited version)

Number 2.3 ..... (edited version)

3. Committee to consider the ethics of human research.....(specify name)..... namely

Number 3.1 ....

.... File recording equipment that is the same as all documents submitted this time.

As allowed by the Food and Drug Administration..... < Company/Agency Name > .....Bring or order drugs into the Kingdom for research (Form N.Y.M.1) Receipt number .... Date of receipt..... For the research project named in Thai..... .... Research project code..... TFDA CT no. ..... (if any) as detailed in attachment number 1

Now, I have received all the results of consideration from the Human Research Ethics Committee. Therefore, we would like to submit the results of the consideration and all related documents and evidence that have been revised according to the opinions of the Food and Drug Administration and the Human Research Ethics Committee.

In this regard, I would like to state that

[ ] All research sites specified in the license have been approved .

[ ] Some research locations specified in the license have not been approved, including: 1) ..... and 2) ..... I would like to notify you of the cancellation of the said research location. and certify that drugs will not be imported for use at canceled research sites

Please be informed accordingly.

Best regards

....

(..... .....)

position .....

Note : Signed by the authorized person according to the requirements in Section 1.1 and marked. ✓Related message page and fill in the correct statements according to the facts

Appendix 14

Progress report submission letter

Company / department header

date..... ...

Subject : Request to submit a progress report of a research project. ..... For the year .....

learn Director of the Drug Division

Refer to the license to import or order drugs into the Kingdom for research, receipt number ...< *specify all requests* >...

Attached items* (1 set) as follows:

Number 1 Research project progress report form

Number 2 .....

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

As allowed by the Food and Drug Administration..... < Name of company/agency > . ...bringing or ordering drugs into the kingdom for research (Form N.Y.M.1) Receipt number .... Date of receipt..... For the research project named..... < Thai name > ....

....

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

Now, I would like to submit a report on the progress of the research project in accordance with the requirements in the relevant announcement of the Food and Drug Administration and attached herewith.

Therefore, I would like to study for your consideration.

Best regards

....

(..... .....)

position .....

Note : Signed by the authorized person according to the requirements in Section 1.1 and fill in the correct information according to the facts.

Appendix 15

Research project progress report form

<table>
<tr><td colspan="3">Research project progress report form
who are permitted to import or order drugs into the Kingdom without registering a drug formula for research purposes</td><td>Research project code
....</td><td>Page ..... of .....</td></tr>
<tr><td colspan="3"></td><td>TFDA CT
no. ....</td><td>Intraday data
..... to .....</td></tr>
<tr><td colspan="5">Refer to Form N.Y.M.1, receipt number .....< specify all requests >..... .....</td></tr>
<tr><td colspan="3">Authorized
person ....
(Please specify the name of the organization/company)</td><td colspan="2">Overall/global status of research projects
[ ] In progress . [ ] Closed as scheduled . [ ] closed early</td></tr>
<tr><td colspan="5">Name of research project in
Thai ....
.....
....
....</td></tr>
<tr><td>Research sponsor in Thailand
name ....
.....
address ....
.....
Telephone/Email .....
....</td><td>Overseas research sponsor
name ....
.....
address ....
.....
Telephone/Email .....
....</td><td>Contract research company (CRO)
name ....
.....
address ....
.....
Telephone/Email .....
....</td><td colspan="2">Research Supervisor (Monitor)
Name-
Surname ....
.....
Affiliation ....
.....
Telephone/Email .....
... .</td></tr>
<tr><td></td><td></td><td>Number of volunteers (people)</td><td></td><td></td></tr>
</table>

Research project progress report form

who are permitted to import or order drugs into the Kingdom without registering a drug formula for research purposes

Research project code	Page ..... of .....
TFDA CT no.	Intraday data ..... to .....

List of research locations	Name of primary investigator	According to the goal	that actually participated	that is in the trial period	within the follow-up	who left the research	Participating in research	Closing date for accepting volunteers to join the project (or approximately) [a]	Date of the subject's last scheduled appointment. (or approximately) [a]	Status of research operations at each research site [b]
1.										
2.										
3.										
N										

* Are there any changes? that falls under Section "4.3 Cases that must be notified to the Food and Drug Administration" and has not yet been notified to the FDA or not? **[ ] do not have . [ ] Yes (attach the clarification letter along with supporting documents)**	** Were there any deviations from the research protocol during this reporting period? [ ] do not have . [ ] Yes (**attach the clarification letter along with supporting documents**)	*** If in doubt or if there is a need/urgency regarding a research project, please contact .... Responsibilities in the project are ..... Tel.....Fax..... .....Email.....

Additional explanation ***a*** In cases where there is a reason that cannot be specified or currently the last volunteer has not been closed. Specify "Unable to specify"	**We certify that all information is true.** .... (..... .....)

<table>
<tr><td colspan="2">Research project progress report form
who are permitted to import or order drugs into the Kingdom without registering a drug formula for research purposes</td><td>Research project code
....</td><td>Page ..... of .....</td></tr>
<tr><td colspan="2"></td><td>TFDA CT
no. ....</td><td>Intraday data
..... to .....</td></tr>
<tr><td colspan="2">b For example: “ Cancelled due to lack of volunteers ” “ In progress ” “ All volunteers have been followed up ” “ Closed prematurely due to..... ” etc.
c Signed by the authorized person according to the requirements in Section 1.1.
Please select a mark.✓ in [ ] and fill in the correct statements according to the facts</td><td colspan="2">position..... .....
As the operator / chief executive of the agency [c]</td></tr>
</table>

Appendix 16

Form for notification of termination/end of research project

Company / department header

date..... ...

Subject: Notification of summary of termination/end of research project

Dear Director of the Drug Division

Refer to the license to produce sample medicine (Por.Yor.8) for conducting research studies on humans. Receive number.....

Attached items* (1 set) as follows:

No. 1 Copy of license to produce sample medicine (Pho.8) for research in humans. Receive number.....

Number... Evidence of return or destruction of medicine.

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

With (name of company/unit) .... Licensee to produce drug samples (P.Yor.8) for research in humans. Receive number .... Date of receipt..... For the research project named..... .... Research project code..... TFDA CT no. ..... (If any) Now the research project has been terminated/terminated. due to*.....

There is summary information as follows:

(1) Project start date .....Project termination/end date...total duration .....

(2) All locations where research is conducted in Thailand are.....

(3) Volunteers who received medicine, number.....people.

(4) Number of volunteers separated by research location as in this table.

List of research locations Number of volunteers (people)
according to the screened goals that actually participated who participated in the research as required who left the research prematurely
1.
2.
3.
N
(5) Procedures for tracking volunteers In the event of termination of the research project Due to the safety of research drugs According to the details in the attachment. number.....

(6) There is a deviation from the research protocol that has not been notified in the research project progress report. According to the details in the attachment. number.....
(7) There is an application for permission. Produce drug samples (Ph.Yor.8) for research in humans. For the research project mentioned above ..... times, the details are as follows.
Ph.Yor.8, receipt number, list of medicines, number of medicines, actual number of medicines at the research institute.

(8) Processing of remaining or expired investigational drugs. Ready to attach evidence
....
....
So I studied to know.
Best regards

....**

(..... .....)

position ....

.

Note: * Please specify the reason for terminating/ending the research.

** Signed by the business operator

Appendix 17

Document self-check form

for requests for corrections and changes Items regarding permission

according to form N.Y.M.1 / P.Y.8 for research studies on humans

Request for change regarding [ ] N.Y.M.1 [ ] P.Y.8 (Research)	
Project ID	
Check number	
date	

Part 1 summarizes the results of document inspection. (Officers only)	
Type of research drug (main) [ ] Biological medicine [ ] Veterinary drugs [ ] Chemical drugs [ ] Others	
Summary of document inspection results [ ] Receive the request (issue the document "Form notifying the results of the consideration of the request") [ ] cannot be edited in Date of submitting the request (issuance of document " Record of defects ")	**Request Inspector** ( ) dated

Part 2 : Advice and Testimonials

Instructions for using the document self-check form

1. Study the requirements in the relevant Drug Division announcements.
2. Prepare documents in accordance with the requirements in the announcement. All items complete Sort by document list
3. Any changes made should be clearly displayed in the document. Or there is good communication so that the appraiser can easily understand.
4. Arrange documents according to the sequence number that corresponds to the form.
5. **Responses to self-inspection results** are as follows:
   - Answer ' **Yes** ' or ' **Yes** ' or ✓means you have checked yourself and it meets the requirements.
   - Answer **'N/A'** or **' Not applicable '.** Upon inspection, it was found that the regulations stated that this document was not required to be submitted.
   - Answer **' Reference... '** or **'Refer ... '** Specify the number receiving the request or the number receiving the request + date of receipt. related

Note ** Leaving blank Because the applicant did not check it himself. Staff will return the request, so if you have any questions about the requirements or document preparation, Please ask the staff **

Applicant/attorney (First name-Last name) ....

On behalf of (company/agency) ....

Call .... Fax :..... ... .E-mail: ....

We certify that we have studied and prepared documents according to the FDA regulations and have prepared every document completely. Sort by list of documents and check yourself according to the table below.

sign ..... (Applicant/attorney) Date..... ....

Part 3 Document check table

clause	checklist	Results of self-inspection	Results of inspection by officials		note
			1st time	2nd time	
*	Acknowledged that it is not possible to apply for changes to the licensee, drug list, or quantity, but must cancel the old license and apply for a new license.				
**	Be aware that 1 request may request changes to only 1 main issue, such as in the case of requesting to extend the validity of medicines. (This is a change in quality and results in a new expiration date label) to be submitted in 1 request, etc.				
***	Every document that is a copy must be certified as a true copy.				
1	**Data recording device (** in the case of submitting paper forms **)**				
	1.1 File copies of all submitted documents (MS word, PDF file)				
	1.2 Excel files for logistics systems				
2	**2.1 Request to amend and change the items regarding permission according to the form N.Y.M.1 / P.Y.8 (Research)** ☐ Paper ☐ e-sub				
	1) The information of those eligible to submit an application matches those of those granted permission.				
	2) Express your wishes				
	3) Research project information (name, code TFDA (permission date from Oct. 2016, except for expanding the scope of BE , the director will not know)				
	4) Specify the main points that need to be revised from, to, and why.				

clause	checklist	Results of self-inspection	Results of inspection by officials		note
			1st time	2nd time	
	5) Are there any other changes related to the main issue? If so, specify from, to, and why.				
	6) Specify documentary evidence				
	7) Risk prevention measures and assurances, such as in the case of changes that may pose a risk to research or volunteers. or in the case of requesting a change due to an error In the case of requesting the use of drugs across research institutes Must certify that evidence will be stored. Make a complete account and can be verified or cases of changes that may cause risks to research or volunteers, etc.				
	8) Signed by the authorized person - the business operator - the highest executive at the department level and above.				
	2.2 Order of assignment of government officials In the case where the highest executive of a ministry or department in charge of disease prevention and treatment, the Thai Red Cross Society or the Government Pharmaceutical Organization There is an assignment to perform duties related to importing or ordering drugs into the Kingdom.				
3	**Power of attorney (** in case of paper submission **)**				
	1) Power of attorney (submit request, clarification, correction, receive document)				
	2) Copy of the identity card of the grantor/passport				
	3) Copy of the identification card of the attorney-in-fact.				
	4) Stamp duty 30 baht per 1 attorney.				
4	**Copy of relevant license 7**				
	1) Complete as specified in the request for amendment.				
	(Add a list of documents as appropriate Ready to check by yourself)				
5					
6					
7					
8					
9					
10					

Appendix 18

Request to amend the items regarding permission according to the form N.Y.M.1 / P.Y.8 for human research studies

Receiving number.....
date.....
Recipient.....

1. I.....
   position .....
   on behalf of
   [ ] Ministry .....[ ] Department.....
   .....
   [ ] Thai Red Cross [ ] Government Pharmaceutical Organization
   [ ] Drug manufacturing licensee name .....license number.....
   .....
   [ ] The licensee brings or orders medicine at the place named, ...license number. .....
2. wish to request Modify and change items regarding permission according to the form
   [ ] N.Y.M.1, receipt number.....
   .....
   [ ] Phor.Yor.8 for human research studies, receipt number.....
   .....
3. For the research project name (Thai language).....
   .....
   .....
   Research project code .....and TFDA CT no.....
   .....
4. Items requested to be changed (choose 1 main item)
   [ ] Information in the license **except** licensee information, drug list and quantity
   [ ] medicine label
   [ ] Medicine documentation
   [ ] Researcher's manual document
   [ ] Volunteer recommendation document
   [ ] Summary of research project
   [ ] Research project details

[ ] Pharmaceutical quality control and production documents

[ ] Other (specify).....

.....

from.....

is.....

due to.....

and [ ] do not have [ ] There have been changes related to the main points above, including:

.....

from.....

is .....

due to.....

5. documentary evidence

[ ] Copy of license according to form N.Y.M.1 / P.Yor.8 for research studies on human subjects.

[ ] medicine label

[ ] Medicine documentation

[ ] Researcher's manual document

[ ] Volunteer recommendation document

[ ] Summary of research project

[ ] Research project details

[ ] Evidence of approval from the Human Research Ethics Committee accepted by the FDA.

[ ] Others include.....

.....

.....

6. Risk prevention measures and guarantees (if relevant).....

.....

.....

sign .... Applicant

(..... .....)

Appendix 19

Sample notification letter

Company / department header

date..... ...

Subject: Notification regarding the importation or ordering of drugs into the Kingdom for research purposes.

learn Director of the Drug Division

Refer to the license to import or order drugs into the Kingdom for research, receipt number .....

Attached items (1 set) are as follows:

No. 1 Copy of license to import or order drugs into the Kingdom for research, receipt number .....

Number 2 ...(specify) ....

...

Number... Recording equipment, data , files that are all the same as the documents submitted this time.

As allowed by the Food and Drug Administration..... < Company/Agency Name > .....Bring or order drugs into the Kingdom for research (Form N.Y.M.1) Receipt number .... Date of receipt..... For the research project named..... < Thai name > ....

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

I would like to notify the Food and Drug Administration of the changes that have been made. Approval/certification from the Research Ethics Committee accepted by the Food and Drug Administration. (Attachment....) with the following items:

1. < Specify what was changed, what was the original, what was changed, reasons, and measures to prevent risks >

2. < Specify what was changed, what was the original, what was changed, reasons, and measures to prevent risks >

So I studied to know.

Best regards

....

(..... .....)

position ....

note : *Signed by the authorized person according to the requirements in Section 1.1 and filled in with correct, factual information.*

Appendix 20

Form notifying summary of termination / end of research project

Company / department header

date..... ...

Subject: Notification of summary of termination / end of research project

learn Director of the Drug Division

Refer to the license to import or order drugs into the Kingdom for research, receipt number .....

Attached items* (1 set) as follows:

Number 1 : License to bring or order drugs into the Kingdom for research purposes. Receipt number: ..... (original)

...

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

With (name of company/unit) .... Licensee to import or order drugs into the Kingdom for research purposes In the research project named..... .... Research project code..... TFDA CT no. ..... (if any) Nowadays there has been a termination / termination of the research project due to *..... .....

There is summary information as follows:

(1) Project start date ... . Project termination / end date ... Total duration .....

(2) All locations where research is conducted in Thailand. ..... namely .....

(3) Volunteers who received medicine, number ..... people

(4) Number of volunteers separated by research location as in this table.

List of research locations	Number of volunteers (people)				
	According to the goal	screening	that actually participated	who participated in the research as required	who left the research prematurely
1.					
2.					
3.					

N					

(5) Procedures for tracking volunteers In the event of termination of the research project Due to the safety of research drugs According to the details in the attachment. number.....

(6) There is a deviation from the research protocol that has not been notified in the research project progress report. According to the details in the attachment. number.....

(7) There is an application for permission according to form N. .Y M. 1 for the above research project ..... times with the following details:

- Receive number, ...date of receipt ..... Number of import requests .....

Name of research drug, ...actual amount imported .....

- Receive number, ...date received.....Number of import requests .....

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

Includes a list of all medicines .....as follows:

1. Name of research drug, ...total amount .....remaining.....
2. Name of research drug, ...total amount .....remaining.....

(8) Processing of remaining or expired investigational drugs. Ready to attach evidence

So I studied to know.

Best regards

.... **

(..... .....)

position ....

.

note : ** Please specify the reason for terminating / terminating the research.*

*** Signed by the authorized person according to the requirements in Section 1.1 and fill in the correct information according to the facts.*

Appendix 21

Criteria and methods for reporting adverse reactions from drugs used in clinical trials.

๑. Definition of words

Definition of terms other than this list Refer to the book ICH Good Clinical Practice Guidelines , Thai version, published by the Food and Drug Administration.

๑.๑ Adverse drug reaction (ADR) means

๑.๑.๑ Adverse reactions from new investigational drugs or investigational drugs for new indications mean All dangerous and unwanted symptoms resulting from any dose of medicine. research The word " caused by medicine " means It is at least reasonably possible to explain that the adverse reaction is due to the study drug. that is It cannot be ruled out that there is no relationship.

๑.๑.๒ Adverse reactions from drugs already on the market mean any symptoms Regardless of the dangers and undesirables that arise from the use of drugs in normal doses, both for prevention and Diagnosis or treatment of disease or to modify the physiological functions of the body

๑.๒ 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 documentation for the drug being used). in research which has not yet been registered as a drug formula Medicine documentation or a summary of drug information that has been registered in the drug formula)

๑.๓ Serious Adverse Event (SAE) or Serious Adverse Drug Reaction means any adverse event. medical condition that occurs when receiving any dose of medicine and causing

(๑) Died

(๒) It is life threatening.

(๓) Must be admitted to the hospital or have to stay in the hospital for a longer time

(๔) permanent significant disability / disablement has occurred, or

(๕) Birth defect / congenital abnormality

๑.๔ The annual safety data cut -off date means The annual due date of the safety data used to prepare the annual safety report.

๒. Expedited Reporting of Adverse Reactions Occurring During Clinical Studies (Expedited Reporting)

Persons who are permitted to import or order drugs into the Kingdom for research purposes / those who are permitted to produce drug samples to request drug registration (Form P.Yor.8) for human research studies. It is responsible for monitoring the safety of investigational drugs. and report to the Food and Drug Administration. with the following requirements:

๒.๑ **Things that need to be urgently reported** include:

๒.๑.๑ Serious unexpected drug reactions found in Thailand caused by research drugs or that has been reported by other regulatory agencies or publications

๒.๑.๒ Other safety concerns include safety information that changes the risk-benefit assessment of investigational drugs. Change the method of giving the medicine or change overall research operations such as

(๑) Unexpected Serious Adverse Reactions that has an increased incidence or severity and considered to be of clinical importance

(๒) Significant harm to the subject, such as the ineffectiveness of a drug used to treat a life-threatening disease.

(๓) Important new information regarding safety from animal studies, such as carcinogenicity

๒.๒ **Reporting deadline**

๒.๒.๑ Serious, unexpected adverse drug reactions that are fatal or life-threatening. Must report within 7 days after the authorized person first receives the information. and submit additional reports within the next 8 days. However, reports will be sent periodically if there is additional information.

๒.๒.๒ A serious adverse drug reaction that was unexpected but not fatal or life-threatening. The report must be submitted within 15 days after the authorized person receives the information for the first time. The report must be submitted periodically if there is additional information.

๒.๒.๓ Adverse reactions that occur after the subject leaves the study or the study has ended. The report must be submitted within 15 days after the authorized person receives the information for the first time. The report must be submitted periodically if there is additional information.

๒.๓ **How to report urgently**

๒.๓.๑ Individual reporting must be submitted through the information system of the Health Product Safety Surveillance Center **(http://thaihpvc.fda.moph.go.th)** , except in cases where the system is unavailable or disrupted. Submit the report as a document to the New Drugs and Drug Research Promotion Group, Drug Division, Food and Drug Administration.

๒.๓.๒ Other reporting Make a book with information, including a summary of the issues. Risk assessment and related details Send new drug groups and promote drug research, Drug Division, Food and Drug Administration.

๒.๓.๓ Individual reporting information Must contain at least the following information:

(๑) Information that can identify volunteers, such as volunteer IDs

(๒) Research drugs

(๓) Adverse symptoms or Results suspected to be related to medication This can indicate that it is a serious and unexpected event.

(๔) Trackable report sources

(๕) Research project code or name of the research project

(๖) Reporting number, such as the reporting number assigned by the research sponsor.

๒.๓.๔ Reporting research cases where treatment is concealed

Submit a report that reveals the subject's treatment code. In the case where the treatment code of that volunteer cannot be disclosed Submit reports that have not disclosed the treatment code and submit reports that reveal the subject's treatment code later, unless the Commission Office deems it appropriate to release the treatment code immediately. Authorized persons must disclose the treatment code to the Food and Drug Administration as soon as possible.

๓. Annual Safety Report and End of Study Safety Report

Those who are permitted to import or order drugs into the Kingdom for research / those who are permitted to produce drug samples to request registration of drug formulas (Form P.Yor.8) for human research studies. They are responsible for monitoring the safety of investigational drugs. and report safety information annually and when research ends by gathering information both domestically and abroad to the New Drugs and Drug Research Promotion Group, Drug Division, Food and Drug Administration. with the following requirements:

๓.๑ Reporting must be made according to the following form.

๓.๑.๑ A letter explaining the safety of volunteers in the research project annually or at the end of the research.

๓.๑.๒ List of Serious Adverse Drug Reactions for each volunteer.

๓.๑.๓ Table summarizing the number of reports including Serious Adverse Drug Reactions, separated by terminology (symptoms and diagnosis).

๓.๒ **Report schedule and reporting methods**

๓.๒.๑ Safety report at the end of the study Must report internally 6 Months after the research end date Submit the report as a document to the New Drugs and Drug Research Promotion Group, Drug Division, Food and Drug Administration.

๓.๒.๒ Annual safety report Must report internally 3 Months from the date of the Annual Safety Data Cut-off Date, submit a paper report to the New Drugs and Drug Research Promotion Group, Drug Division, Food and Drug Administration.

Annual safety report book or when research ends

Write at (name of agency/company, address, telephone number)

date .....

Subject: Clarifying the safety of volunteers in annual research projects/when research ends

Dear Head of New Drugs and Drug Research Promotion Group

Attached 1. List of serious adverse drug reactions for each volunteer.

2. Table summarizing the number of reports including serious adverse drug reactions separated by terminology.

According to the agency/company .....As someone who is allowed to [ ] Bring or order drugs for research purposes (N.Y.M.1) [ ] Produce drug samples (P.Yor.8) for research studies in humans.

Research project name.....

.....

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

There is a list of N.Y.M.1 students who are permitted as follows:

1. Dated .....number.....
2. .....

have collected and analyze safety data and report adverse drug reactions of such research [ ] annually or [ ] when the research ends. which includes information between.....

To date, ...I would like to clarify and summarize important issues. as the following topic

1. **Safety analysis (Emphasis on newly discovered issues)**

   .....

   .....

2. **Benefit-risk assessment (Emphasis on evaluating impacts on volunteers/volunteers)**

   .....

   .....

3. **Risk management measures**

I'm here to inform you. If you have any questions or suggestions, (Agency/Company) is willing to cooperate fully.

Signed---

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

(Line Listing of All Suspected Serious Adverse Drug Reactions)

Reporting Period		Research project name (Protocol Name)
[ ] Annual (Annual)	together with Intraday data	.....
[ ] End of Study	..... to	.....
	.....	.....
		.....
Number of adverse reactions reported (Numbers of Reports).....		.....
		Research project code (Protocol Code No .) .... TFDA CT no. .... (if any)

Volunteer ID (Subject Identification)	Case Reference No.	Country _	Age _	Sex _	Daily dose (Daily Dose)	Date of Onset	Date of receiving the medicine (Dates of Treatment)	Adverse Reaction	Patient's Outcome	Notes (Comments)	Results of opening treatment data codes (Unblinding Results)

Table summarizing the number of reports including serious adverse drug reactions by terminology (symptoms and diagnosis).

(Aggregate Summary Tabulation of All Serious Adverse Drug Reactions)

Reporting Period		Research project name (Protocol Name)
[ ] Annual (Annual)	together with Intraday data	.....
[ ] End of Study	..... to	.....
Number of Adverse Reactions Reported (Numbers of Reports).....		Research project code (Protocol Code No .) ..... TFDA CT no. .... (if any)

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

Body Systems / Terminology of Adverse Reactions **(Body system / ADR term)**	***Investigational drug 1*** ***(Study Drug 1)***	***Investigational drug 2*** ***(Study Drug 2)***	***Research drug ...*** ***(Study Drug ...)***	***Investigational drug N*** ***(Study Drug N)***	**Placebo** **(Placebo)**	**Medicines that conceal treatment** **(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.*