Regarding the Study and Research on Drugs for the Purpose of Providing Information to Support Drug Registration and Approval[1]

Authority: **Thai Food and Drug Administration**

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[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

1. Introduction

To fully understand the requirements for compliance with the regulation outlined in this announcement, it is essential to clarify the terminology employed within the Ministry of Public Health's guidelines. These definitions are integral to comprehending the fundamental criteria, procedures and conditions governing the study and research of pharmaceuticals, specifically in relation to data collection for registration purposes:

"Clinical research" refers to research conducted with human subjects for gathering data that can serve as the basis for the creation of registration documents for the research drug involved.

"Clinical researcher" refers to individuals who support or conduct clinical research in Thailand.

"Sponsor of clinical research" refers to individuals or organizations that hold responsibility for initiating or funding clinical research and the management of the funds used.

"Drug" refers to products used in research, whether medicinal or non-medicinal, and whether these are administered for testing or as part of research analysis.

"Study Results" refers to products, substances or agents, used for testing or as a reference in drug studies, including products that have been registered and are being used or transformed into new forms or in new formulas that are not authorized or that are being examined under testing procedures or have not yet been authorized for use.

"Research Participant" refers to individuals who are part of the research team studying drugs. They play a significant role and may have key decision-making authority regarding important matters related to the study of drug research.

The ethical standards in clinical research are defined by criteria and conditions that ensure safety, security and confidentiality. These are set by recognized regulatory institutions and are fundamental in ensuring that the research is conducted according to established medical and scientific standards. Data collected in the process of drug research is protected to ensure accuracy, safety and ethical use. This includes regular audits and reviews to ensure that the integrity of the research process is maintained.

The ethical review committee plays an important role in overseeing research involving drugs, ensuring that the process meets legal and ethical standards, and that research participants are not exploited.

2. Standards for Drug Research Studies

In addition to the provisions outlined in the standard for conducting rigorous clinical drug research, the latest edition emphasizes the requirement for compliance with relevant national laws and regulations. It also underscores the importance of enhancing the capacity of research participants to engage in drug studies that adhere to the national standards and guidelines for drug safety management. This includes safeguarding the rights, safety and well-being of participants, while ensuring that the results of the research are credible and trustworthy.

Considering this, the Ministry of Public Health has established supplementary standards to guarantee alignment with national regulations and has issued comprehensive guidelines to further clarify these requirements.

2.1. Standards for Sponsors of Clinical Drug Research Studies

a. Sponsors of clinical drug research studies must meet the qualifications outlined in the Ministry of Public Health's regulations regarding the guidelines and conditions for conducting clinical drug research. These regulations govern the procedures for the registration of drug trials as per the 2023 decree. Sponsors are defined as "individuals or legal entities, registered in Thailand, either within the public or private sectors, who are responsible for the initiation, management, organization or funding of drug research studies." In certain instances, the sponsor of a drug research study may be a legal entity or organization based outside of Thailand, provided they are authorized to support drug research activities in accordance with established agreements with local entities. Accordingly, Thailand requests that sponsors of drug research studies broaden their scope to include those who qualify as "Collaborative Sponsors of Drug Research Studies".

b. Responsibilities of Sponsors in Clinical Drug Research Studies:

(1) The sponsor must ensure the provision of insurance coverage or compensation for the participants, such as reimbursement for medical expenses, treatment costs, loss of time or any other form of compensation.

(2) The sponsor must ensure that the information provided in the investigator's manual or documentation related to the research is presented in a clear, concise and easily understandable manner. This should facilitate the investigator's comprehension and assessment of the research's potential risks and safety.

(3) The sponsor should establish a research methodology that complies scientific principles. The sponsor should ensure that drug production adheres to high standards and that the study undergoes rigorous testing in accordance with the relevant scientific guidelines.

(4) The sponsor must ensure that the safety of the drug is continually evaluated throughout the study and that any risks associated with the drug are communicated during the entire research period, including the development phase.

(5) The sponsor is responsible for promptly informing the investigators of any safety concerns that may arise during the study, including any findings that may negatively impact the participants or alter the progress of the research.

(6) The sponsor must establish a quality assurance and quality control system in the clinical drug research study to ensure that the study's processes, documentation and reports comply with the most recent study protocols and relevant regulatory guidelines.

(7) The sponsor must ensure the registration of the clinical drug study on an authorized registry platform, which may include websites for research registration within the country (e.g., Thailand's clinical research registry website) or other international databases that comply with the standards and laws governing clinical research.

(8) The sponsor must obtain approval for the research and provide the researchers with the results of the ethical review and approval process for each research site.

(9) The sponsor must ensure that the research continues to adhere to the approved protocol, even if there are changes in the study's methods after approval. Such modifications should be carefully evaluated and authorized before being implemented.

(10) The sponsor is responsible for preparing and submitting progress reports on clinical research, including updates on any adverse events or complications related to the drug under investigation. Final reports should be submitted at the end of the study, accompanied by relevant documentation on the outcomes and safety data.

(11) The sponsor must establish and implement appropriate safety measures and emergency protocols to prevent and mitigate risks to the research participants. Any risks or safety concerns must be addressed promptly; and participants should be provided with the necessary information and approval to proceed with the study.

c. The sponsor may assign responsibilities to individuals with appropriate qualifications; however, the sponsor cannot disclaim partial or full responsibility.

d. In cases of drug research that involves collaboration with a sponsor, the joint sponsor must assume the following responsibilities:

(1) Acknowledge the relevant provisions of the applicable laws;

(2) Carry out various activities as stipulated in the terms of the collaboration agreement with the sponsor of the drug research;

(3) Ensure the execution of activities that allow the joint sponsor to comply with the legal provisions in relation to the research;

(4) Exchange critical information with the sponsor of the drug research to support compliance with the established legal requirements, such as reporting any incidents that may negatively impact the research participants' safety, adverse event reports or other violations that may have implications for the research process or the safety of participants.

2.2. Standards for Principal Investigators

a. The principal investigator must possess the following qualifications: be a Thai national, have completed relevant education, training and have sufficient experience to properly carry out the functions required in conducting the research.

b. The principal investigator must take on the following responsibilities:

(1) Obtaining approval for the pharmaceutical research from the relevant authorities and notifying the research sponsor results of the review before starting the research study.

(2) Conducting research in accordance with the ethical principles outlined in the latest version of the Helsinki Declaration (2011) and complying with the relevant laws and regulations.

(3) Performing research activities following the guidelines approved in the research framework.

(4) Considering the rights to safety and the well-being of research participants as a priority; balancing scientific and societal benefits.

(5) Ensuring that researchers or those receiving the research assistance are qualified, appropriately trained and certified with professional qualifications within Thailand, and that they are responsible for managing and making decisions in their respective fields of expertise.

(6) Ensuring that the management and administration of drug collection, use and disposal in research adhere to scientific principles to maintain quality and safety, with records maintained for future verification, tracking and auditing.

(7) Ensuring that researchers or participants using drugs in the research comply with the approved research framework from relevant authorities.

(8) Preventing the destruction of critical research documentation by following regulations and maintaining important records of the research process, especially those related to drug use.

(9) Taking immediate actions to address and eliminate any risks or harm that arise during the study, especially those that affect the well-being of participants.

2.3. Standards of Research Institution

a. Research institutions must have at least one principal investigator or more. In any case, at least one person must be the principal investigator.

b. Research institutions must be hospitals or healthcare institutions that operate under the government, public or private sectors. These institutions must meet the requirements as established by relevant laws, including the Ministry of Public Health, other government agencies or the National Health Security Office; otherwise, they must be recognized as proper healthcare institutions by the law.

c. In cases where research is not conducted in a hospital, the Food and Drug Administration (FDA) Office may consider granting permission for such institutions to proceed, provided they adhere to the conditions specified in the law. The institution must meet the safety standards outlined in the most recent guidelines.

d. In case of research related to the study of biological substances, the institution must undergo accreditation according to the guidelines set by the Food and Drug Administration Office. This accreditation is necessary to ensure proper research procedures are followed.

2.4 Standards for Conducting Drug Research

a. The sponsor of pharmaceutical research shall arrange for the output or instructions for the research study to be provided to the principal investigator after receiving approval for the pharmaceutical research study from the Department of Health and Drug Administration.

b. The pharmaceutical researcher shall start the research study once they have received both the approval from the relevant authority and confirmation of receiving approval for the pharmaceutical research study. This confirmation should be documented in the registration process, including receipt confirmation.

c. The pharmaceutical researcher must use the pharmaceutical products or drugs involved in the research only after obtaining approval for the research study.

d. Authorization will end only in the case of: the research study is completed, the sponsor of the pharmaceutical research study decides to withdraw the study approval or the pharmaceutical research department withdraws the approval based on specific conditions, as outlined in the relevant regulations. The approval may be extended for a period of no longer than 5 years.

e. The researcher must ensure the integrity of the pharmaceutical research process by adhering to the following guidelines:

(1) Avoid fabricating, altering or misrepresenting data or results from the research.

(2) Ensure transparency and honesty in the communication of the research findings.

(3) Do not compromise the ethics or objectivity of the research due to personal biases or external pressures.

f. The researcher must ensure the quality of the research based on scientific principles by:

(1) Formulating research questions that are based on current scientific knowledge.

(2) Applying appropriate scientific methodologies.

(3) Ensuring that the research is conducted with proper resources, materials and infrastructure.

g. The researcher must conduct the research following the most recent and relevant ethical and scientific standards.

h. The researcher, responsible for collecting personal data in pharmaceutical research, must adhere to measures that protect the confidentiality and privacy of personal data, especially concerning research participants, and must ensure:

(1) Limiting access to personal data only to authorized individuals.

(2) Protecting against unauthorized changes, disclosures or uses of the data.

(3) Documenting actions taken to ensure the data is managed properly.

i. Researchers who collect and maintain biological data related to the research must:

(1) Adhere to the principles outlined in Section h.

(2) Ensure that the collection and maintenance of biological data are conducted appropriately, in accordance with the established guidelines of the field.

(3) Safeguard the necessary resources required for the collection and maintenance of biological data as specified in the guidelines.

3. Requesting Permission for Drug Research Studies

3.1. Eligibility to Submit a Request

a) Eligible applicants may be sponsors who possess the qualifications and duties as specified in the Ministry of Public Health's announcement regarding the criteria, methods and conditions for drug research to gather data for drug registration approval under the Drug Act B.E. 2566 (2023), as well as additional standards outlined in this announcement by the Food and Drug Administration (FDA).

b) A drug research project must have only one applicant for approval, except in cases where the research is conducted through direct collaboration between: a foreign government organization; an international organization or a non-profit foreign organization; and any of the following entities in Thailand: government agency, state enterprise, public organization or other government-affiliated entity.

If there is a necessity to submit separate applications for drug research approval, this must not obstruct or circumvent compliance with relevant laws and standards for drug research. Additionally, it must ensure the protection of volunteers and the integrity and reliability of research data.

3.2. Classification of Drug Research Studies

Drug research studies are classified based on risk levels into three categories, as follows:

a. Category A: Low Risk or No Greater Risk Than Standard Treatment

Includes:

(1) Drug research where the investigational drug has already been registered and approved in Thailand, and its use aligns with the registered indications, dosage, administration method and target population.

(2). Bioequivalence studies.

b. Category B: Moderate Risk or Somewhat Higher Risk Than Standard Treatment

Includes:

Drug research where the investigational drug has already been registered and approved in Thailand but differs from the approved registration in terms of indications, dosage,

administration method and target population (excluding studies involving children and pregnant women, which fall under Category C).

c. Category C: High Risk or Significantly Higher Risk Than Standard Treatment

Includes:

(1) Drug research not included in Categories A or B.

(2) Research on advanced medical products (such as gene therapy, cell therapy and tissue engineering products) that do not qualify under Category A.

(3) Drug research identified by regulatory authorities as having particularly high risks, such as: Drugs that may pose greater safety concerns in the Thai population compared to other nationalities, newly developed innovative drugs, research projects with inherently high-risk characteristics.

3.3. Application Submission Process

a. Applicants must review the requirements outlined in this announcement before preparing the necessary supporting documents.

b. Applicants should initially determine the research category of their drug study according to the classification described in Section 3.2.

c. Applicants must prepare the required documents for completing the drug research study application form through the electronic submission system, along with all supporting documents as specified in this announcement.

d. Applicants must use the self-assessment checklist provided for drug research study applications (available on the Drug Regulatory Authority's website) to ensure completeness and accuracy of all submitted documents.

e. All applications must be submitted through the Drug Regulatory Authority's electronic submission system.

3.4. Required Documents for submission

Below is a table[2] summarizing the required documents for drug research study applications, categorized based on risk levels:

No.	Required Documents	Category A	Category B	Category C
1.	Form ศย.1	✓	✓	✓
2.	Principal Investigator's Declaration (for each research site)	✓	✓	✓
3.	Proof of Insurance or Compensation Plan for research participants in case of injury, disability, or death caused by the study	✓	✓	✓
4.	Complete Research Protocol	✓	✓/P	✓/P
5.	Ethical Approval Document from a recognized ethics committee	✓	✓	✓
6.	Drug Procurement Statement	✓	✓	✓
7.	Proof of GMP Compliance from a certified drug manufacturer	/	✓	✓
8.	Participant Information Sheet and Informed Consent Form	*	✓	✓
9.	Research Drug Label	*	✓	✓
10.	Investigator's Brochure or Drug Dossier	*	✓	✓
11.	Quality Control & Manufacturing Documentation	*	*	✓
12.	Regulatory Approval from International Agencies (if available)	N/A	✓	✓

3.5. Duration of Results Notification

Once a request passes the review process into the system, the request will enter the approval process for assessment, with a set period as per public guidelines or websites related to the sector.

[2] **Notes:** ✓ = Required, "/" = Must be submitted with the application, "(ถ้ามี)" = Required only if relevant, "P" = Can be submitted after approval, "*" = Not required for initial application but must be available for inspection, N/A= Not applicable.

3.6. Specific Requirements for Application Forms and Supporting Documents

a. Guidelines Related to Research Application for Approvals

(1) Applicants: The applicant must provide contact information, including their phone number. This individual must have the appropriate qualifications to be a supporter of the drug research study, according to the definitions provided in the Ministry of Public Health's regulations, which specify the methods and conditions for conducting drug research studies and registering the data.

(2) Supporting Data from Research Participants: This includes data from participants both in Thailand and abroad, as some studies may involve individuals, organizations, or groups located in other countries or abroad, assisting in supporting the drug research. The guidelines specify that information about the supporting individuals should be included in the application form. There may be more than one supporting party or sponsor listed, ensuring that full details of all supporting entities are provided as part of the application.

(3) Name of the Research Project in Thai: This should match the approval document from JE 3/56. The title of the research project should be accurately reflected in the official application document for all relevant research institutions associated with it.

(4) Name of the Research Project in English: This should correspond with the English draft of the research project.

(5) Research Project Code: This is a code assigned by the sponsor of the drug research study, and the same code should be used consistently in all research institutions involved in the same research project.

(6) Abbreviation or other names (if any)

(7) Duration of the Research Project: Please specify the duration as either a specific time period (e.g., 1 year, 2 years, etc.) or the total number of research cycles and specify if the research is being conducted for the first time.

(8) Type of Drug: Reference to the details in section 3.2 for a detailed classification.

(9) Reference to Evaluation Results: This section refers to the results of the evaluation from the regulatory body responsible for overseeing the research. Supporting documentation should be included and more detailed information is available in the relevant appendix.

(10) Research Ethics Group: The group responsible for overseeing ethical standards in the research.

(11) Research Registration: Registration of the research study will help ensure transparency and prevent any confusion in publishing or reporting the results.

(12) Country where the Research is Conducted: Indicate whether the research is conducted in Thailand or multiple countries.

(13) Number of Research Sites: The total number of research sites involved in global study.

(14) Number of Research Participants: The total number of participants across all global research sites.

(15) Number of Research Sites in Thailand: Indicate the number of research sites in Thailand.

(16) Details from Each Research Site in Thailand: Each research site within Thailand should provide complete information.

(17) Start Date of the Research in Thailand: Indicate the starting date of the research within Thailand (approximately).

(18) End Date of the Research in Thailand: Indicate the ending date of the research within Thailand (approximately).

(19) Financial Support: Documentation showing the source of financial support for the research should be provided, especially in relation to the research proposal or participant registration documents.

(20) Evidence of insurance or compensation arrangement: For accidents resulting in injury, illness, disability, or death due to research involving drugs, evidence of insurance or compensation for expenses such as medical costs, hospital fees and lost work time should be provided. This may include a document from the insurance company or an agreement form specifying the responsible parties and their shared liabilities, including compensation payment.

(21) Individuals or organizations that are responsible for overseeing the research (e.g., IT department or similar).

(22) Companies or organizations that manage research programs.

(23) Companies or departments that manage data.

(24) Individuals or organizations with a responsibility to ensure safety.

(25) Laboratories performing tasks related to research should be registered and recognized as facilities conducting specific tasks, either domestically or internationally, including all labs that handle safety, such as those for medical or pharmacological tests.

(26) Types of drugs used in research as part of the main research program.

(27) Information on the drug used in research (including any data required under the research program) is divided into:

1. Drugs or substances imported into the national system for research by an authorized recipient must show a record of the drug (which may be one type or multiple types together based on the purpose of the research, such as drugs prepared for medical trials) and any related information necessary for the importation of the drug into the system.
2. The production of drugs within Thailand for research purposes, including a record of the drug (which may also be one or multiple types based on the research's goals, such as drugs prepared for medical treatment trials), and all necessary information regarding the production for research purposes in Thailand.

Additionally, confirmation of the research's approval can be provided in the form of a request for approval using a designated form, confirming receipt of approval for the research. This approval must ensure that the results of the research, whether for drug production or other purposes, comply with research regulations. The form does not require additional documentation beyond what is necessary for registration in the national research system.

b. Conditions for the Acknowledgment of the Principal Investigator for Each Research **Site** The acknowledgment of the principal investigator at each research site for research conducted in Thailand must follow the acknowledgment format for compliance with the regulations and conditions of the research study. Each principal investigator must provide an acknowledgment at the research site in Thailand (see detailed information on the drug website) and submit it in one set of documents for each investigator.

c. For clinical research, evidence must be shown to guarantee insurance or provide compensation for the following: medical treatment, hospitalization, loss of working time or other compensation for damages. This applies to the research participants or individuals entitled according to the law. If the research participant becomes sick, injured, or suffers permanet disability or death as a result of clinical research, it may be covered by insurance companies or agreements outlining responsibilities and liabilities, including compensation costs.

d. Guidelines for the Complete Research Proposal

(1) The research proposal must be written in Thai or English.

(2) The proposal must have received approval from the relevant authorities, and there must be no pending approval.

(3) Must include detailed information in each section, ensuring all points are fully covered and follow the order according to document 607.

e. Guidelines related to the approval documents for research studies from the IRB/IEC

(1) The principal investigator at each research site is responsible for requesting approval to conduct research from the relevant authority. The approval must be obtained before starting any research activities.

(2) Must be done in accordance with Announcement No. 8/66 and with the regulations of the Food and Drug Administration, including the procedures and conditions for the approval of the Ethics Committee for the review of clinical research projects related to drugs and the publication of the list of names and websites.

(3) Supporters of the research must apply for approval from the Ethics Committee, the approval document must be in the Thai language. The application for approval must include the following details:

-The name of the principal investigator and the affiliated institution as per the regulations of the Food and Drug Administration and their corresponding research project.

-The name of the institution where the study is being conducted.

- The research proposal, along with relevant documents that outline the ethical considerations and necessary research procedures.

- The research's approval duration and/or any expiration dates of the research project.

- The research proposal and relevant documents, including an updated version of the "Form 50" that the Ethics Committee has reviewed and approved.

- The time frame for the research approval and/or the expiration date of the research must be clearly indicated.

(4) Research studies must apply for approval from the Ethics Committee (JE3/50). The approval will be granted upon submission of the request as per the designated procedure.

(5) For research studies of type C and situations that occur during the review process of JE3/50, the supporter of the research may apply for approval to conduct research following the procedure outlined. The approval can be granted subsequently.

f. Regarding Drug Supply Statement

(1) A supporter of research on medicinal products may organize research activities through various methods, including importing or instructing the import of medicinal products into the country for the purpose of research, such as studying medicinal product results for research or disposing it from the market in the country, as specified in the related form. In all cases, such activities must be conducted in a logical and responsible manner, ensuring proper justifications.

(2) The supporter of the medicinal product research must prepare a statement of disposal, dividing the main points into three sections, which align with the method of disposal described.

-If importing or instructing the import of medicinal products into the country for research purposes, the details must be provided along with a clear justification for conducting the research, including any results from the use of the medicinal products. If the research cannot be verified or if the period for conducting the research expires, it is recommended that the data be assessed within a maximum period of five years, with possible adjustments of up to 20% or as per relevant circumstances.

-The results of the medicinal product research should be available in the form of a detailed report.

- Disposal from the market in the country, if applicable, should also be reported with details.

g. Evidence of drug production according to Good Manufacturing Practices

(1) The research sponsor is responsible for procuring investigational drugs or co-administered drugs that are manufactured in compliance with GMP (Good Manufacturing Practices) standards.

(2) Drugs procured through manufacturing, importation or ordering in Thailand for the purpose of drug research must be accompanied by: a certificate of pharmaceutical manufacturing standards compliance (GMP), a certificate of pharmaceutical product compliance, an evaluation report issued by a regulatory authority and other documents or evidence demonstrating certification of drug manufacturing standards for investigational drugs. Therefore, drugs referenced for foreign drug registration using other types of evidence, such as official website records, do not require certification of compliance with drug manufacturing standards (GMP) or certification of pharmaceutical product compliance. However, verification must confirm that the drug has been registered with the same strength, dosage form and manufacturing site as the drug used in this research study.

(3) In the case of drugs used in clinical research phase 1, an exemption from GMP inspection and evaluation is granted. Instead, a self-declaration letter must be submitted by the individual responsible for the quality assurance system.

(4) Drugs procured from the domestic market in Thailand that have a valid drug registration number and come from an authorized source do not require the submission of documentation proving compliance with Good Manufacturing Practice (GMP) standards.

h. Documentation Requirements for Volunteers and Informed Consent Forms

(1) Approval must be obtained from the relevant ethics committee. However, in cases where approval is pending, submission of the version under review is acceptable.

(2) The language used must be appropriate for the volunteers. For instance, Thai volunteers must be provided with a Thai-language document, while foreign volunteers may use documents in their native language, accompanied by a certified in Thai or English translation. The translation must be verified to ensure that the content is consistent with the original language.

(3) Documents used for providing information and explanations during the informed consent process, as well as the informed consent forms and any additional materials given to volunteers, must include details in accordance with the latest version of the relevant regulatory guidelines. Additionally, the total estimated number of volunteers participating in the research project, as well as the number of volunteers from each institution in Thailand, must be specified.

i. Drug Label Requirements

(1) Submit the label or an image of the label for every type and size of the drug product, with a design similar to the actual label being used.

(2) Use the Thai language, except for the drug name/code and details about the sponsor of the research project. In this case, either Thai or English may be used. In cases of drugs managed by an individual or pharmaceutical company, either Thai or English may be used.

(3) The label must include the drug's name or code, size, strength, form and packaging method. If the drug is part of a clinical trial or involves investigational use, the label must explicitly state: "This drug is a counterfeit or [Drug Name / Drug Code] + [Dosage Strength]", or a similar statement. This ensures that the drug is properly identified and that it complies with the regulatory standards for clinical research. Additionally, the label must include:

-The research project code or the name of the research project.

-The production batch number or a code for tracking the stages of the production process.

- The label may also include a certification or registration number, if applicable.

- The drug's usage method can reference additional instructions, such as usage logs, or the individual responsible for the drug's management.

- Contact information, such as the phone number of the research sponsor or organization.

- A clear statement that the drug is for clinical research only, or a similar phrase.

- The label must specify the condition under which the drug is stored or handled.

- The expiration date or duration of use for the drug, in the appropriate format (e.g., by month/year or the specific duration of research trials).

- The label must specify that the drug should be kept out of reach of children.

(4) For labels on primary packaging when combined with secondary packaging, the following information should be included:

- Drug Name / Drug Code: Along with dosage strength, dosage form, and route of administration.

- Investigational Drug Code or Project Name: This helps identify the specific project or trial.

- Product Batch and/or Investigation Sequence Number: To specify which batch the drug belongs to and its position in the clinical trial process.

- Labeling Requirements: These may include marks like "Investigational Drug" or the specific label regarding clinical trial use, ensuring compliance with regulations.

(5) For packaging that is in the form of a blister pack or small unit with an area of no larger than 3 square inches (including when the primary and secondary packaging are combined), the following information must be included on the label:

- Route of Administration: While this may not always need to be specified for certain types of packaging, it should be included in the case of specific dosages or routes of delivery.

- Investigational Drug Code or Project Name: To identify the clinical study or trial associated with the product.

- Product Batch and/or Investigation Sequence Number: To ensure traceability and correct identification of the batch or stage in the trial process.

- Labeling Marks: Marks such as "Investigational Drug" or other identifiers to indicate its investigational status, in accordance with regulations.

- Sponsor's Details: The name of the sponsor or contract research organization conducting the clinical trial.

(6) The labeling of investigational drugs must adhere to the standards specified in the location where the approval for the drug's production and usage has been granted. These standards must also comply with the Ministry of Public Health's regulations and be aligned with current guidelines regarding the labeling of investigational drugs. This includes:

- Proper Approval: Ensure that the drugs have been approved for production and distribution following the established regulations.

- Compliance with Regulations: Follow the specific protocols and requirements outlined by the Ministry of Public Health, including detailed labeling criteria related to the investigational nature of the drug.

- Standards for Drug Labeling: The drug must be labeled in accordance with current practices, including those laid out in regulations from 2016 (B.E. 2559) regarding clinical trial drugs and investigational products.

- Updates and Amendments: The guidelines for labeling investigational drugs may be updated, and any changes to these guidelines must be followed as per the official regulations published by the relevant health authorities.

(7) In the case of preparing medicine for use in a research station, a label must be attached to the container that will be used to manage the medicine. This includes preparation, mixing or injecting the medicine, as well as preparing a dosage for administration. It is necessary to ensure that the research personnel or individuals in charge are confident that the primary researchers or those who have received approval are managing the process according to the regulations

- Arrange to make a label that contains suitable and accurate information according to the objectives of the research project.

- Arrange to make a standard operating manual or an appropriate standard method in preparing the medication and labeling the medication, following the guidelines and methods in the current guidelines.

- Proceed with the procedures following the guidelines by a pharmacist or a professional in the health science field from the research facility that has been approved in a proper manner.

- There must be documented evidence of the actions performed, including an inspection by two individuals, for example, under the supervision of the control process, to ensure careful management of the labeling process.

- Retain the documentation and records related to the process to support the inspection by the authorities, either from a regulatory agency or a relevant medical institution. In this case, the

applicant is not required to submit the label along with the application. However, they must ensure that the primary researchers or those who have received the approval are carrying out the process according to the regulations and are prepared for inspections or audits of the research activities.

(8) In the event of a justified request, the applicant may seek consideration for the relaxation of the conditions related to labeling as outlined in the preceding sections under specific circumstances, including the following:

-Information on the label may be supplemented by references to other documents, such as methods that cite the use of medicinal references or related records, by appending the referenced documents along with a detailed explanation.

- The addition of labels after the production or importation of medicinal products into Thailand should be done in accordance with the prescribed regulatory requirements for medicinal research labeling. This label, or the design of the label, must closely resemble the original and should be affixed at the location where the production or labeling activity occurs, contingent upon receiving the necessary approvals. However, in the presence of mitigating factors, the request for such adjustments may be reviewed, with conditions placed on who may oversee the proper implementation of these adjustments, in accordance with established standards. This process should be conducted under the supervision of a qualified pharmacist or health professional from the research institution who has received proper authorization.

- The label utilized in medicinal research studies should conform to the regulatory guidelines prescribed by relevant authorities, which may include additional references, such as those found in the “N.Y. 1” or “P.Y. 8” formats for human trials.

(9) Request for Exemption from Labeling Requirements: In the case where an exemption from labeling requirements is requested as outlined in Section 8, the applicant must utilize the designated form for requesting an exemption from medicinal labeling requirements, which is specifically provided for such cases (see detailed information on the relevant website). In all instances, consideration must be given to the safety rights and the well-being of individuals who participate in clinical research, with particular emphasis on the integrity of the clinical trial process. Ensuring that the safety and credibility of the medicinal product involved is of utmost importance.

(10) In the event of a request to amend the duration for which the labeling of a medicinal product remains in effect, the applicant must submit a label or an image of the label that is congruent with the format of the existing label used for the original product. The original label may remain, provided it is updated to reflect the new duration of use without obscuring the prior product information. This process must take place in locations authorized to conduct activities related to the production and distribution of medicinal products in accordance with the established regulatory framework.

Should any exceptional circumstances arise, the applicant may request an exemption from the standard labeling requirements. In such cases, the modification must be carried out in compliance with the applicable conditions as stipulated by the relevant authorities. The procedure for the modification must involve competent professionals, including licensed pharmacists or other qualified individuals in the health sector, ensuring that the actions undertaken align with public safety standards and uphold the integrity of human health protection.

All steps in this process must be documented and verified by independent experts to ensure compliance with quality control protocols. Furthermore, the request must be submitted using the official form for modifying labeling requirements, which is available on the designated website for medicinal product registration.

(11) Drugs used in accordance with the framework of a research protocol and utilized following the specified instructions that have been officially registered in Thailand, must be drugs that are prohibited from being sold on the Thai market. There must be no grounds for these drugs to require further regulatory procedures or market approval beyond their usage as stated in the existing approved documentation, and they must not be marketed under a different label.

I. Guidelines for the Research Investigator's Manual (or Investigator's Brochure) and Supplementary Information

(1) In order to ensure the accuracy and currency of the information pertaining to the ongoing clinical trials or investigational medicinal products, it is imperative that the sponsor or investigator consolidates the most recent and relevant data. This should encompass the status of the investigational drug or therapeutic approach, including regulatory approvals, as well as any updates regarding its clinical development. For investigational drugs not yet included in the Investigator's Brochure, this information must be appropriately documented and reviewed. The sponsor must provide timely and comprehensive data from clinical trials or other pertinent research, ensuring that all data is current and reflective of the most up-to-date scientific understanding.

(2) If the data referenced in the research study includes information not yet in the Investigator's Brochure or research protocol—such as results from animal studies or studies involving investigational drugs that have not been tested in humans—it must be added to the study documentation. If this supplementary data is incomplete, insufficient, or inconclusive, the investigator should formally request additional information to support the research application. This request for more data should be submitted to the relevant regulatory or ethical review committees for further evaluation and approval.

(3) Procedures for Submitting Summary Documents:

- For Research Involving Non-Commercial Investigational Drugs: For investigational studies that do not involve marketed drugs, the investigator is required to submit an Investigator's Brochure, referencing the relevant data and ensuring it adheres to the regulatory standards. In cases where the investigator submits a request for the "Certificate of Compliance with Good Manufacturing Practices (GMP)" or other related certifications, the submission should reference the registration of the investigational product in the country of origin or in other countries where the product is being utilized. The submission should include documents that align with the standards of the regulatory body in that jurisdiction.

- For Collaborative Research Involving Investigational Drugs: For investigational drugs used in collaborative research, especially those involving multi-country studies, the researcher must submit the Investigator's Brochure along with additional supporting documents. This includes certification from the relevant regulatory bodies or national authorities, ensuring that the investigational product is authorized in the countries where the research is being conducted. The documents must also refer to compliance with the relevant regulatory framework on "Good Clinical Practices (GCP)" or other applicable quality control procedures, aligning with the ethical standards required for the study.

- For Research Contributing to Academic or Professional Advancements: In cases where research data is used for academic, scientific or professional purposes; it is necessary to submit additional research materials or documentation that were not previously outlined in the Investigator's Brochure. This submission must be based on current published studies or trial data, and it should provide clear evidence of adherence to ethical guidelines and institutional review board (IRB) requirements.

(4) Investigator's Brochure Submission Guidelines:

- Review and Update Frequency: The Investigator's Brochure should be reviewed and updated at least once per year. Revisions should be made in accordance with any changes in the regulatory requirements, scientific advancements or the ongoing development of the investigational drug. Regular updates will ensure that the information remains current, particularly regarding new findings, efficacy data and safety updates. It is important to revise the brochure as necessary to reflect new information, such as the introduction of new studies or advancements in the drug's development.

- Documentation of Review and Approval: The investigator is required to submit documentation that confirms the Investigator's Brochure has been reviewed and approved. The documentation should include formal approval from the appropriate regulatory institutions and must include the version number and the approval date. Any delays in approval or pending statuses should be clearly outlined to avoid miscommunication. The investigator must submit the finalized version of the brochure once it has been approved by the reviewing body.

- Additional Supporting Documentation: In addition to the Investigator's Brochure, the investigator must submit supplementary documentation as necessary. This may include any additional research findings, safety reports or updated clinical trial data that have been generated since the last submission. This information should be presented in a clear, organized manner and should comply with the established formatting standards.

m. Guidelines for the Document of Drug Quality Control and Production Performance

(1) Submit the document for quality control and drug production performance for all drugs used in drug research studies, which must be in accordance with the specifications outlined.

(2) The submission of documents for quality control and drug production performance is divided into 2 main approaches, with detailed information provided in the table for the submission of documents for quality control and drug production performance.

Standing documents, quality control and pharmaceutical production	
New Chemical Entity (NCE) or Chemistry Manufacturing and Controls (CMC) Include:	
	1.The Gene document presents the qualitative information of the drug NCE, covering various topics as specified in the list of prescribed topics. It serves as a guide for different phases of research. 2. For the "Attestation that the dosage form was manufactured under Good Manufacturing Practices (GMP) conditions", a copy of the GMP certificate issued by the Pharmaceutical Regulatory Authority of Thailand must be provided. This certificate must confirm the certification of the drug category for which the production permit is being applied and must be valid (not expired). This document also serves as supporting documentation for the request mentioned in Item 7.
References and external links	
(1)	The pharmaceutical registry retains its status as a reference. Supporters of drug research studies must ensure that investigational drugs or comparator drugs have undergone proper manufacturing and production processes. The company must verify that the same quality control standards and manufacturer are used as those listed in the drug registry of Thailand. This information can be referenced by specifying the registration number and reference details **of** the drug formula in Form S.E.1.

(2)	International Pharmaceutical Registration with Certificate of Pharmaceutical Product (CPP) / Certificate of Free Sale (CFS) Supporters of drug research studies must ensure that investigational drugs or comparator drugs have undergone proper manufacturing and production processes. The company must verify that the same quality control standards and manufacture are used as those listed in the CPP/CFS and confirm that the drug is available under these certificates. The market availability in the respective country can be referenced accordingly. References to CPP/CFS should be specified in S.I.1. a. For CPP submissions, the content must align with the Model Certificate of a Pharmaceutical Product issued by the World Health Organization (WHO) and must be valid (not expired). b. For CFS submissions, the certificate must confirm that the drug has been registered and marketed in the country of origin and must include a valid supporting document.
(3)	Reference to the Registration of Medicines Abroad with Supporting Evidence from Pharmaceutical Regulatory Agencies (NRA) Supporters of drug research studies must ensure that investigational drugs or comparator drugs have undergone proper manufacturing and production processes. The company must verify that quality control standards and the manufacturer are the same as those listed in the proof of registration issued by the relevant National Regulatory Authority (NRA). Additionally, the required attachments should include: • The Food and Drug Commission's declaration. • Relevant standards. • Licensing documentation. • Reports related to drug research studies. • Specify other evidence references that indicate the registration of medicines from the NRA in the NRA. • Other proof of registration from the National Regulatory Authority (NRA) may include information printed from the NRA website where the drug is registered, or official documentation from the drug regulator, such as a registered drug label.

(3) Due to the organization of research and the concurrent use of medications, multiple approaches may be employed, including the registration status of the medication and the citation of the registered medication. Consequently, the submission of various documents and the identification of the medication producer in the form of S.1, Section 4 (medication data) must be in accordance with relevant evidence. This should follow the guidelines outlined in the table summarizing the relationship between the approval of quality control documents and the production of the medication, as well as the identification of the medication producer in the form of S.1, Section 4, as detailed below.

	CMC Gene	Pharmaceutical data document	Identification of pharmaceutical manufacturers in S. E.1
1	NCE + GMP Certificate	IB + / - more information	As indicated in NCE
2	References and external links	PI of pharmaceutical recipe registration References (+/- IB +/- more info*)	As specified in the National Pharmaceutical registry English
3	CPP/CFS references	PI of pharmaceutical recipe registration References (+/- IB +/- more info*)	As indicated in CPP/CFS
4	Evidence of registration NRA pharmaceutical recipes	PI of pharmaceutical recipe registration References (+/- IB +/- more info*)	As specified in the page/ Pi / label/ Sources relating to registration Reference dosage

n. The regulations regarding the supporting evidence for the evaluation results of the quality control department on the medicines should be conducted as outlined in Appendix 3.

o. Regulations regarding the delegation of authority and the power of attorney.

Delegation of authorities submitting requests via the electronic system to be processed through the specified channels.

3.7 Amendment or additional documents based on the evaluation

If the evaluation results from the assessor require the applicant to make amendments or clarify certain issues, the applicant or the authorized representative must take corrective actions or provide clarifications according to the evaluation results within the specified time by submitting a written explanation of the amendments along with relevant supporting documents through the electronic system.

3.8 Submission of IRB/IEC approval and related documents

For research studies of Type C and the sponsors of the research, the evaluation results from IRB/IEC at the location must be submitted within 15 days from the date the evaluation results are received from IRB/IEC at the location. The relevant documents must be submitted using the form for submission of evaluation results from IRB/IEC at the location (see detailed information on the website of the [name of the organization]). These must be accompanied by the evaluation results in Thai and the relevant supporting documents in the research project that has been revised based on the feedback from the Food and Drug Administration Office and the Food and Drug Board, along with the corrected parts.

3.9 Guidelines for Document Requirements in Urgent Public Health Cases

It is important to note the significance of clinical drug research, especially in cases of urgent necessity due to public health emergencies, such as severe infectious diseases, in order to benefit the public. Therefore, clinical research is essential for the development of new medicines to prevent or treat diseases that are currently problematic and for which there are no available treatments on the market. Based on recommendations from the World Health Organization's expert committee, the evaluation system of research in each country must comply with international standards. This ensures that urgent clinical research studies can be considered for approval swiftly and appropriately for public health emergencies.

A public health emergency refers to an urgent situation that affects the safety and well-being of the public in the country, as declared by the public health authorities. In such cases, the approval for conducting drug research can be expedited through a waiver of documents, which must have the aim of addressing the public health emergency that exists at that time.

The request for approval should use Form 1 and include a supporting document as specified, along with a request for a waiver of certain requirements in the application for research approval in cases that are urgent for public benefit (as detailed in the annex). This request for

a waiver should be based on appropriate justifications, clearly stating the reasons for the urgency.

Researchers who have received approval for research involving urgent public health matters, through an expedited procedure, must prepare and submit a progress report on the research every month, starting from the date of approval. Additionally, they must comply with the further specific conditions outlined in the research approval, apart from following the usual research procedures.

4. Post-approval procedures

a. Reporting Research Progress:

(1) The primary researchers must report to the Ethics Committee on the progress of the research in a timely manner, at least once a year, or as determined by the Ethics Committee, but not later than one year.

(2) The researchers must submit an annual progress report to the Office of the Food and Drug Administration, covering the period from October 1st to 31st of each year. Before the conclusion of the project, researchers must use the format for reporting progress of the research project as outlined in Appendix 5 and send it via the electronic system to the Food and Drug Administration.

b. Extension of Research Authorization:

In order to continue the research, data must be submitted to renew the research authorization. Typically, for research that concludes after five years, the authorization will expire at that time. If the research authorization was granted for a period of five years but the research remains incomplete, or if an extension is necessary, an extension may be requested based on valid grounds. However, the extension cannot exceed an additional five years.

The procedure to apply for the extension of the research authorization must follow the format outlined in Form 2 and be processed via the Food and Drug Administration's electronic system.

c. Managing changes in Research:

Changes or modifications are divided into three categories, as follows:

1. Changes that are essential and must be promptly carried out to eliminate any immediate risks.

2. Changes that must be notified for awareness.

3. Changes that require a request for modification before proceeding with the actions.

Additionally, researchers and supporting staff are responsible for monitoring and verifying that any changes comply with the established guidelines and do not introduce unnecessary risks. They must also ensure that the security and reliability of the study and its data are maintained.

(1) Changes that are essential and must be promptly carried out to eliminate any immediate risks: Refers to the changes that the researcher deems necessary to take immediate action to eliminate specific risks that have arisen concerning the safety of participants before receiving approval from the relevant authority.

Summary table of actions required when researchers must take immediate action to eliminate specific hazards

1	Changes that need to be made immediately to eliminate specific hazards on a page should be addressed by researchers as soon as possible. Specific duty hazards may occur to volunteers before approval by the IRB/IEC. There are guidelines implemented by key researchers and supporters of drug research studies.	Types A	Types B and C
(1)	The principal investigator must notify the sponsors of the immediate action taken, the reasons for the action, the corrective and preventive measures (CAPA). This notification should also be sent to the IRB/IEC. The IRB/IEC must be informed within 7 days of the date of the event, even if it does not provide an immediate response or action within its review period.	yes	Yes
(2)	Sponsors of drug research studies are required to inform the IRB/IEC of the actions taken, the reasons for those actions, the corrective and preventive measures (CAPA). This must be done within 7 days of the date of the event and the information should be approved or commented on by the IRB/IEC.	*	Yes

Note: For a Class A drug research study, drug research sponsors are not required to notify the action and reasons for the study. However, pharmaceutical researchers must maintain records of various evidence documents to accommodate inspections from the pharmaceutical division or regulatory authorities.

Methods for implementing immediate changes to eliminate specific hazards:

1. Proponents of drug research studies should evaluate and certify any necessary changes based on the guidelines outlined above to address specific hazards.
2. For Type B and C research studies, a form must be created to inform relevant parties about the required changes. Immediate action should be taken to eliminate specific hazards, with changes supported by evidence-based guidelines.
3. Electronic documents must be submitted within 7 days from the date the hazard is identified and must be approved by the IRB/IEC.
4. Principal researchers must follow the IRB/IEC guidelines and ensure that sponsors adhere to these guidelines for approval and acceptance.

(2) Changes that must be notified for awareness: This refers to the meaning of changes that the research sponsor must inform others about to ensure they are aware. In certain cases, this should be done after receiving approval. Researchers and supporting personnel must carefully consider and take the necessary actions, including implementing measures to manage and prevent potential risks. This process is essential to maintain the safety of the data and ensure the reliability of the information, in compliance with the relevant rules and regulations.

2.	Changes to be notified	More information
(1)	Any changes to the information in Sl.1, whether accompanied by proof, must be approved by the IRB/IEC at FY. Changes include: -Supporters of joint pharmaceutical research (both Thai and foreign). - Research registration (only in Thailand or research in many countries Country). -Total number of participating research locations around the world according to plan. -Total number of volunteers worldwide according to plan.	- Proof of approval must be attached.

	-Number of joint research sites in Thailand as planned. -Date of initial research in Thailand (approximate). -The final date of research in Thailand (approximate). -Individuals or organizations that supervise research. -Companies or organizations that manage research projects. -Information management company or organization. -A person or organization whose responsibility is to assess safety. -Laboratories. -Cancel or reduce research facilities. -Changes in the method of supplying a common drug. -Change information pills of supplying with how to supply the drug from the market.	
(2)	Change of information in Sl.1 to attach proof of approval from the IRB/IEC. Changes include: -Thai language research project name. -English research project name. -Project code. -Project abbreviations. -Main researcher name and contact information.	-Proof of approval must be attached. -Proponents of the research must be attached. -Corresponding documents to support such changes must be attached.

	-Increase/decrease the number of volunteers in the research. -Financial support. -Proof of insurance or arrangement of various compensation payments if volunteers suffer from illness, injury, disability or death as a result.	
(3)	Evidence must indicate that insurance or other arrangements are in place for compensation payments, including medical expenses, work-related costs or loss compensation. If a volunteer experiences illness, injury, disability or death as a result of drug research, appropriate compensation must be provided.	- Proof of approval must be attached.
(4)	The research project detail document must be approved by the Ethics Committee at FY. However, special conditions may apply in certain cases.	- Proof of approval must be attached.
(5)	Information documents for volunteers and consent documents.	-Proof of approval must be attached.
(6)	Researcher's handbook.	-Proof of approval must be attached.
(7)	Drug documentation.	-Proof of approval must be attached.
(8)	Pharmaceutical labels were previously permitted in the following cases: 1. When changing the format while maintaining the full text in compliance with all requirements. 2. When amending the name, address or phone number of the research sponsor, a contracted research organization or a researcher. 3. When correcting spelling errors.	-Supporters of drug research studies must also be verified and certified.
(9)	Modify the Drug Substance manufacturer information for chemical drugs in quality control documents and pharmaceutical production records.	-Supporters of drug research studies must be verified and assured.

(10)	Extending the lifespan of research drugs or co-use drugs in cases where stability studies have been conducted. A stability protocol must be followed, and analytical results must comply with stability specifications in accordance with the licensed drug research study.	- Supporters of drug research studies must be verified and certified.
(11)	Transfer of imported drugs from one research site to another under the same project drug research study.	- Supporters of drug research studies must implement management measures to prevent potential disruptions and ensure proper documentation. -Evidence must be securely stored and records must be complete and verifiable.
(12)	To manufacture new original research drugs for use in the initial research project without making changes to quality control documents or pharmaceutical production processes.	-Show Reasons and Necessity. -Show the part where there is a change.
(13)	Notification of Clinical Research in Thailand must be submitted to the Department of Clinical Research. Overseas pharmaceutical supervision, whether initiated independently or otherwise, must be reported as soon as possible.	-Supporters of drug research studies must be informed as soon as possible.
(14)	Report on drug research and suspension.	
(15)	Notification of the early termination of a research project must be provided, along with the reason for termination, if the project is concluded before the planned timeline.	
(16)	Any deliberate violation of ICH-GCP guidelines or the research framework that may significantly impact on the safety or integrity of participants, whether physically or mentally—must be reported to the Department of Pharmaceutical Research. Supporters of drug research studies are required to notify the authorities of the corrective and preventive measures (CAPA) implemented to address and mitigate such issues.	-Supporters of drug research studies shall notify the corrective measures and Protection (CAPA).

Note: Supporters of drug research and key researchers must implement appropriate management measures for all changes made, ensuring the strict prevention of any potential disruptions or noise. This is essential to maintain volunteer safety and ensure the reliability of data, in compliance with ICH GCP guidelines and regulatory requirements.

Methods for Notifying Changes:

1. Proponents of drug research studies must carefully evaluate and certify any changes that occur, ensuring they comply with the guidelines mentioned above.
2. A notification form should be created to inform relevant parties about the change, clearly outlining the change and providing supporting evidence, as per the guidelines.
3. Electronic documentation must be created within 15 days of identifying the change or receiving the IRB/EC notification. It must be approved or accepted if required.

(3) Changes that require a request for modification before proceeding with actions: This refers to changes that the sponsor of the clinical research must submit a request for modification and approval before continuing with the research process. The sponsor is responsible for verifying and certifying that the proposed changes fall within any applicable exceptions. Additionally, clinical researchers must assess and implement stringent measures to manage and mitigate any risks that may arise, ensuring the safety of the volunteers and the credibility of the data, in compliance with legal requirements and operating procedures when changes occur.

3	Changes that must stand amendment requests and be permitted first	More information
(1)	Change of information in SI model1. - Phases of research projects. - Therapeutic area. - Add research facilities. -Types of key research drugs of the project. -Pharmaceutical data used in drug research studies.	- Proponents of the research must attach.
(2)	Add or edit the notification label to know.	-Show Reasons and necessities. -Show the section that is Changed.

(3)	Quality control documents and pharmaceutical production. - Change the manufacturer of Drug Substance or Drug Product Biopharmaceuticals or drugs. - Change of manufacturer for Drug Product intended for pharmaceutical research studies or imported pharmaceutical supply. - Extension of the shelf life of an investigational drug or placebo for stability study purposes.	-Show Reasons and necessities. - Show the section that is Changed.
(4)	Change of recipe or product specification.	
(5)	Application for renewal of pharmaceutical research license to bring up information.	- Display the execution status and Reasons to apply for renewal.
(6)	Other changes that do not engage in "notification changes to be made"	- Show the reasons for necessity. - Show the part where there is a Change. -Prevent potential noise.

Note: For all changes made, sponsors of drug research and key investigators must assess and implement appropriate measures. Strict management and preventive actions should be taken to minimize potential variability, ensuring the safety of volunteers and the reliability of data in compliance with ICH GCP and regulatory requirements.

Method for Implementing Changes Requiring an Amendment Request

1. Assessment and Compliance
    - Proponents of drug research studies must evaluate any proposed changes, ensuring they are reviewed and certified as compliant with regulatory standards.
    - A risk-based approach should be applied when considering modifications.
2. Single Request per Main Issue
    - Each amendment request should address only one primary issue.
    - For example, extending the shelf life of a drug (as a quality-related change) and updating the expiration date labeling should be submitted as a single request.
3. Preparation and Submission of Amendment Requests
    - Gather all necessary information and prepare the amendment request for the modification of a Pharmaceutical Research Study (PR-2) or Clinical Trial (CT-2) Form as outlined in Appendix 6.
    - Ensure all required supporting documentation is attached in accordance with the guidelines specified in this notice.

4. Document Verification
    - Use the Manual Document Confirmation Form for research study modification requests.
    - Refer to the Pharmaceutical Division website for specific details on document verification and submission procedures.
5. Electronic Submission
    - Submit the amendment request through the official pharmaceutical regulatory electronic system for processing and approval.

d. Reporting Adverse Drug Reactions:

The reporting of adverse effects or safety concerns from drugs used in clinical research should follow the procedures outlined below:

(1) The Principal Investigator must promptly report any safety concerns or adverse effects from the drugs used in clinical research to the relevant authorities, in accordance with the established guidelines.

(2) The Research Sponsor must ensure the timely reporting of adverse effects or safety concerns from the drugs used in the clinical study, following the established criteria and methodology for reporting any adverse effects.

e. Reporting Study Completion, Suspension or Termination:

Once the research study in Thailand is completed according to the established criteria, or if the research study is terminated before meeting the set criteria or suspended, the following procedures must be followed:

(1) Reporting When the Research Study in Thailand is Completed According to the Criteria: The research sponsor must prepare and submit a summary report of the research progress (Appendix 8) to the FDA within 60 days from the date of the final closure of the research site. The researcher must inform the IRB/IEC of acceptance within the specified time or not exceeding 60 days.

(2) Reporting when the research study is temporary suspended:

- Reporting when a research study is temporary suspended, which may occur at the research sites in Thailand or in certain countries abroad, and which may affect the continuation of the research in Thailand.

- The supporters of the research study must report the temporary suspension of the research study in various situations by sending a notification letter along with the cause of the suspension within 15 days from the date of receiving the notification through electronic systems.

- The principal investigator must notify the relevant authorities about the suspension within 15 days from the date in which the notification is received, in compliance with the established guidelines or regulations.

(3) Reporting when the research study is terminated before the schedule deadline:

- Reporting when the research study is terminated before the scheduled deadline: This applies to situations where a research study is terminated earlier than planned, either at any research facility in Thailand or due to incidents abroad that may affect the research process in Thailand.

- The sponsor of the research must report the termination as follows: (a) Prepare a letter to notify the termination of the project before the scheduled time, including the cause and a plan for managing the research participants, within 15 days after receiving notification. This must be submitted through the electronic system. (b) Prepare a report summarizing the project's termination, including the final outcomes, reasons for early termination, and any documents related to the termination. This report must be submitted to the relevant authority within 60 days of the termination's completion.

- The principal investigator must report the termination or completion of the research project before the scheduled time, along with the cause and a plan for managing the research participants, within 15 days of receiving the notification. The report must be submitted via the specified procedure.

5. Guidelines for Monitoring Drug Research Studies

The Office of the Food and Drug Administration has procedures for monitoring drug research studies that have been approved for research purposes to gather information supporting drug registration. This monitoring can occur before, during, or after the completion of the research, including after the disclosure of the research project.

The person responsible for the approved research study should maintain communication with the researcher to receive notifications of scheduled inspections, allowing for prior monitoring of the inspection procedure with a minimum of 7 days' notice. However, exceptions may apply in cases where the Food and Drug Administration issues special instructions for conducting inspections in accordance with specific regulations. The sponsor of the research study must cooperate and facilitate the inspection process for the authorized officers, following the instructions provided by the relevant authorities:

- Notifying the relevant parties, such as the principal investigators and the officials in the ethics review committee involved in the research process, to ensure they are informed.

- Appointing a representative to serve as the main contact person with the inspection team, facilitating the preparation of audits for the research study.

- Sending the necessary information to the inspection team in accordance with the report provided in the official notification of the research audit, within the specified time frame.

- Preparing equipment and various locations as follows:

1. A meeting room for the opening and closing sessions of the research audit, to be used on the first and last days of the audit process, as per the schedule.

2. A room for the inspectors to carry out the audit, review documents, and access other necessary materials during the audit period.

3. A computer or terminal capable of connecting to the system for recording and reporting participant information in the research project, including original documents and patient data (e.g., forms), where applicable.

4. A location designated for each stage of the research process related to the audit, such as the audit room, operation rooms, and data storage rooms.

- Preparing documents and other relevant information in electronic format, if required as part of the research audit process.

- Preparing the necessary documents according to the status of the research project, including permission documents from the Department of Food and Drug Administration, at the research site.

- Ensuring meals and drinks are provided for participants during midday, ensuring they are safe, hygienic and meet the required standards.