**IRB Submission Form**

**Phyathai-Paolo Hospital Group Institutional Review Board**

**Suggestions for IRB Submission Form**

1.***Italic Text***is a suggestion text / characteristic that must be followed (If you understand the suggestion text, you candelete the text from the IRB Submission form)

✓

2. The Item that is a multiple choice, please put in the space that corresponds to your information.

**IRB Submission Form**

**Phyathai-Paolo Hospital Group Institutional Review Board**

**Protocol identification and Investigator**

1. **Project title** ............................................................................................................................................................................
2. **Name of Principle Investigator** ................................................................................................................................................

**Position**..................................................... **Department**.........................................................

**Hospital**................................................... **E-mail** .................................. **Tel**..............................

 **Educational degree**........................................................................

 *(Please also provide your curriculum vitae)*

* 1. **Responsible research work**

Number of research projects currently under responsibility……………………projects

Expected number of participants/volunteers under responsibility totaling……………………. persons.

**Experiences in ethical issues in research involving human subjects**

❏Experiences in research ethics training in (year) ………………..… *(attached the certificate)*

❏Experiences in Good clinical practice training in (year) ………… *(attached the certificate)*

*(Researcher should attend the training once every three years.)*

* 1. **Researcher’s conflict of interest with organization sponsoring the research/ research drugs/research devices** (such as having share/or family members have shares in the sponsoring company, being a consultant, obtaining honoraria, travel reimbursement, other financial support from the funding source)

 ❏ No ❏ Yes, please specify…………………………………………………………………………………………………..

1. **All Co-** **Investigators**

**3.1 Name of Co-Investigator**....................................................................................................................................................

**Position**..................................................... **Department**.........................................................

**Hospital**................................................... **E-mail** .................................. **Tel**..............................

 **Educational degree**........................................................................

 *(Please also provide your curriculum vitae)*

* **Experiences in ethical issues in research involving human subjects**

❏Experiences in research ethics training in (year) ……………..…… *(attached the certificate)*

❏Experiences in Good clinical practice training in (year) ………… *(attached the certificate)*

*Please provide the document with reasons to IRB committee in case of no certificate in ethics training.*

* **Co-researcher’s conflict of interest with organization sponsoring the research/ research drugs/research devices** (such as having shares/or family members have shares in the sponsoring company, being a consultant, obtaining honoraria, travel reimbursement, other financial support from the funding source)

 ❏ No ❏ Yes, please specify…………………………………………………………………………………………………..

**3.2 Name of Co-Investigator** *(see 3.1)*

1. **Research Funding**

 ❏No ❏ Applying for funding (please specify the funding source)………………..………………

 ❏Research fund was granted\*

 ❏ Government (please specify) …………………...………….……..….…….……..….……..……..………...

 ❏ Private (please specify) ………………………………...……………………………..………….……….....

 ❏ NGO (please specify) ………………………………………..………...……………….………….……….…

 ❏ Other (please specify) ………………………………………......….………………….……………..……… Address of funding source ..............................................................................................................................

 Name of coordinator of the funding source..................................................................................................

 Telephone (which can be reached in and after office hours)...................................................................

 E-mail address: .....................................................................................................................................................

1. **Research Site**

❏ Single center, please specify...............................................................................................................................

❏ Multiple centers

❏only in Thailand

 *(Please specify every institute that takes part in the research project, number of participants/volunteers and the result of IRB consideration in each institute)*................................................................................................................

 ❏collaboration with overseas

*(Please specify the country and every institute in Thailand that take part in the research project, with number of participants/volunteers and the result of IRB consideration in each institute in Thailand)*

..........................................................................................................................................................................................

1. **Duration of research project**

For the whole project …………….……………....………Years........................Months

Duration of data collection …………….………………Years........................Months

*(Researcher can start collecting data only after obtaining the IRB approval.)*

1. **This research is a part of education: for degree, diploma or independent study**

 ❏ No

 ❏Yes, please specify…………………………………………………………………………………………………………………

Obtained the approval from the program committee (Thesis) or supervisor

❏dateobtained ...................................... ❏ not obtained

1. **Summary of proposal; Submit with the full proposal**
	1. **Background and Rationale**

*(Please explain the important content; the content should comply with the research proposal if you have attached it.)*

..................................................................................................................................................................................................................................................................................................................................................................................................

* 1. **Objectives**

....................................................................................................................................................................................................................................................................................................................................................................................................

* 1. **Research category** (can choose more than one items)

❏Experimental biomedical / clinical research: please specify

 ❏ Drug trial phase.....................please specify drug name..................................................................

 ❏ Registered drug *(please attach drug registration or drug leaflet)*

 ❏ Investigational (new) drug

 ❏ Medical device trial, please specify device name .................................................................................

 ❏ Registered device (please attach device registration or device leaflet)

 ❏ Investigational (new) device

 ❏ Vaccine trial phase.................... please specify name/code of vaccine...........................................................

 ❏ Registered vaccine *(please attach vaccine registration or vaccine leaflet)*

 ❏ Investigational (new) vaccine

 ❏ Experimental procedure / intervention, please specify......................................................................................

 ❏ High Risk ❏ Minimal Risk

 ❏ Bioequivalence

 ❏*In vitro* / laboratory-based study

 ❏ Research using repository of biological products (cells, blood, tissues, fluids, etc.)

 \*Specify kind/quantity/number of products use .....................................................................................................

 ❏ Observation clinical research

❏ Prospective (cohort) study

❏ Case series

❏ Retrospective (chart) review

*(Attach the letter of permission to use the medical records from Head of Department/Division with the submission form)*

❏ Epidemiology Research

 ❏ Surveillance

 ❏ Monitoring

❏ Others (please specify) ....................................................................................................................................

 ❏ Social / Behavioral research

❏ Questionnaire-based research

❏Others (please specify)………………………………………………………..……….. ...........................................

* 1. **Research design**

❏ Randomized-controlled trial

❏ Quasi-experimental study (manipulation and control only, without randomization)

❏ Pre-experimental study (manipulation only, without control and randomization)

❏ Prospective cohort study

❏ Descriptive study

❏ Cross-sectional study

❏ Pilot study

❏Others(please specify).....................................................................................................................

* 1. **Research subjects**

**Sample Size Calculation,**

*Please specify the background of sample size in each group. If the fixed formula has been used, please show the formula for calculation and indicate the variables used in the formula with references*

................................................................................................................................................................................................................................................................................................................................................................................................

**Inclusion Criteria**

................................................................................................................................................................................................................................................................................................................................................................................................

**Exclusion Criteria**

................................................................................................................................................................................................................................................................................................................................................................................................

**Withdrawal or Termination Criteria**

................................................................................................................................................................................................................................................................................................................................................................................................

**Subject allocation**

................................................................................................................................................................................................................................................................................................................................................................................................

* 1. **Research Process**

*Please specify research procedures, research devices, steps of research process, things that participants/volunteers must do or be treated (such as number of blood drawn, amount of blood drawn, number of appointments, time consuming for participation in the study). If the research proposal is attached, the wordings in Thai and English versions must be the same, including the reference pages in the relevant proposal.*

................................................................................................................................................................................................................................................................................................................................................................................................

* 1. **Data collection process**

*Please provide case record form, and/or questionnaire, and/or interview question, and/or telephone script to obtain consideration (if any).*

**Data collection must be started after obtaining the IRB approval**

*The case record form must not indicate name, Hospital Number (HN) or any identifications that link to individual subjects,(using the code instead).*

..............................................................................................................................................................................................................................................................................................................................................................................................

* 1. **Outcome measurement / data analysis,** *including statistics used in the research*

..............................................................................................................................................................................................................................................................................................................................................................................................

* 1. **Evidence, data or references** *(writing references should be complied with the international standard)*

..............................................................................................................................................................................................................................................................................................................................................................................................

**Ethical Consideration**

1. **Characteristics of participants/volunteers**

❏ Healthy volunteers

❏ Patients excluding vulnerable subjects

❏Others such as Retrospective chart review

❏ Vulnerable subjects\*, please specify the subject who cannot make decision by himself or

 ❏ children under 18 years \*\*

❏disabled

 ❏ emergency patient or ICU patient, palliative care patient

 ❏ chronic patient who must be in care of doctor or care taker

 ❏ pregnant woman ❏students ❏prisoners

 ❏ armed force ❏person in the foster home ❏ illiterate person

 ❏ others (please specify) ……….....................................................................................................................

Describe additional safeguards to protect the rights and welfare of vulnerable subject .………………………………………………………………………….…………………………………………………………………………………………………………………………………………………………………………………………………………………………..

\* If the participants/volunteers are the vulnerable subjects and the researcher needs the consent from the legal representative, to whom he expects to obtain the consent.

Please specify ………....................................................................................................................................................................

\*\* In case of children ages 7-12 years, the assent may be obtained directly from the children, in addition to the consent from guardian or legal representative.

\*\* In case of children ages over 12 – under 18 years, the assent must be obtained directly from the children, in addition to the consent from guardian or legal representative (except in some cases such as mental retardation)

1. **The usage of medical records/specimens of the participants/volunteers**
	1. **Having permission for using repository of medical products from authorized person**

 ❏ No ❏ Yes ❏ not related

* 1. **Having permission for using participant/volunteer specimens for future used**

 ❏ No ❏ Yes ❏ not related

* 1. **Having specimens sending out of the institute**

❏ No ❏ Yes ❏ not related

**Having specimens sending into the institute**

❏ No ❏ Yes ❏ not related

*(The Material Transfer Agreement must be performed in both cases of item 10.3 and a copy must be provided to the IRB committee prior to obtaining the IRB certificate of approval.)*

1. **Recruitment Process**

**11.1 Research site:** *Please specify where and how potential subjects will be approached for participation in this study*:

..............................................................................................................................................................................................................................................................................................................................................................................................

 **11.2 Process**

 **11.2.1** A person who invites the volunteers to take part in the research

❏ Principal investigator ❏ Co-investigator ❏ Research assistant (such as research nurse, student)

❏ Physician in charge of the patient ❏ Others, please specify.......................................................

*\* The principal investigator who himself provides treatment to the patient should not invite the patient to take part in the research directly because it might cause undue influence. To minimize the possibility of coercion or undue influence, the persuader and basic information provider must not be directly an influential person to the participants/volunteers.*

 **11.2.2** Describe in detail the invitation process for participants to take part in the research such as the approach to participants/volunteers, data access, including the tools used in the invitation and media use (if any);\* *attach the advertisement of subject recruitment and telephone script for consideration*

..............................................................................................................................................................................................................................................................................................................................................................................................

*\*Media use such as the advertisement of subject recruitment and telephone invitation must contain the wordings showing that the participant/volunteer’s participation is voluntary without undue influence. (The advertisement must contain the approval stamp before advertising.)*

1. **Informed Consent Process**

🞍The person who will provide consent or permission………….……..………………………………………….………………

🞍Any waiting period between informing the prospective participant and obtaining consent………………………..………

Participant have opportunity to consider before obtain the consent ……………………….……..………..……………….…

🞍The language understood by the prospective participant or the legally authorized representative………………..…..…

🞍The language used by those obtaining consent ……………………………………………….………………………….……

🞍How to keep subject’s privacy and confidentiality, ❏Where .........................................................................................

**12.1 Relevant documents** (you can choose every relevant item)

 ❏ Participant information sheet and ❏ Informed consent form

 ❏ Participant information sheet and assent form for children ages 7-12 years attach with the participant information sheet and consent form from guardian/legal representative

 ❏ Participant information sheet and assent form for children ages over 12- under 18 years attach with the participant information sheet and consent form from guardian/legal representative

 **12.2 Process: Describe in detail about the consent form process from the volunteer and/or legal representative**

 **12.2.1** A person who asks for the consent from the volunteers for taking part in the research (you can choose every relevant item).

❏ Principal investigator ❏ Co-investigator ❏ Research assistant (such as research nurse, student)

❏ Physician in charge of the patient ❏ Others, please specify........................................

 **12.2.2** Describe in detail the informed consent form process from the participant/volunteer’s or legal representative

..............................................................................................................................................................................................................................................................................................................................................................................................

*\*In case of obtained informed consent form legally representative. Research team must reobtain informed consent again (reconsent) from research participant whenever his/her ability is regained.*

1. **Benefits expected to gain from research**
	1. **Benefit to individual participant/volunteer**…….…………………………………………………………………….……………
	2. **Benefit to profession as a whole**…………………………….……………………………………………………………………
	3. **Benefit to social welfare**…………………………….………………………….…….………………………………….…………
	4. **Others** …………………………………….………………………….…………………………………………………….………..
2. **The impact which may occur to participant/volunteer and compensation**
	1. **Describe whether there are the physical, mental, social and economy impacts especially the risk, or not.**

*(Are there any research identical to the proposed proposal and any adverse events occurred? Please explain in details the opportunity that the adverse event may occur from the information and reviewer assessment) including the inconvenience and wasting time*

..............................................................................................................................................................................................................................................................................................................................................................................................

* 1. **Regulation for protection and correction as well as additional safeguards to protect the participants rights and welfare prepared by the researcher if the adverse event occurs**

.............................................................................................................................................................................................................................................................................................................................................................................................

* 1. **The person who is responsible for the expenses/compensation on the correction or treatment incurred by the adverse event. If there is an insurance policy.**

*(If the researcher is a Phyathai-Paolo Hospital Group employee and does not obtain funding from the private agency, he can indicate Phyathai-Paolo Hospital as responsible organization in case of adverse event occurs)*

.............................................................................................................................................................................................................................................................................................................................................................................................

* 1. **Name of responsible person or physician and telephone number that can be reached at all time in case that the adverse event occurs from the research**

............................................................................................................................................................................................................................................................................................................................................................................................

* 1. **How does the researcher inform the physician in charge or other physicians who provide treatment to the participant/volunteer about his taking part in the research if it is the clinical trial or the research used the diagnostic results such as laboratory, pathological and radiological results?**

............................................................................................................................................................................................................................................................................................................................................................................................

Remarks: in study with intervention to the participants, researcher should put the study code, investigator name, and telephone number in patient's medical records.

* 1. **The research that is monitored by the Study Monitoring and, Data Safety Monitoring Board (DSMB)**

❏Yes, please specify.......................................................

 ❏ No ❏ Not related

* 1. **Other alternative treatments**

❏Yes, please specify.......................................................

 ❏ No ❏ Not related

* 1. **Is there any plan of interim analysis for the risk of the whole project?**

❏Yes, please specify.......................................................

 ❏ No ❏ Not related

1. **Does the research involve or impact on the religion, belief, tradition, culture or good reputation of the institute, local or country that the research is conducting?**

❏Related to, please specify the protection and the way to reduce such impact.................................................................

❏Not related

1. **The method that will ensure the confidentiality or privacy of participant/volunteer** (Tick ☑ to every relevant item)
	1. **a Will the consent process take place with the subject in a private area or room?**

❏yes ❏no (if not, explain: \_\_\_\_\_\_\_\_)

 **b Will the study procedures take place in a private area or room?**

❏yes ❏no (if not, explain: \_\_\_\_\_\_\_\_)

**16.2 Personal case record**

❏No personal case record of participant/volunteer

❏Having personal case record of participant/volunteer (must answer item 16.3)

Please use the code instead of name and personal data of participant/volunteer with no specification of date, month and year of birth, the initial letter of the first name and the last name

❏ Electronic file ❏ Photos/still photos ❏ Video/moving images

❏ Audio tapes ❏ Others, please specify ....................................................................................................

**16.3 If the personal information has been used as mentioned above, please specify the persons who can access the information, duration of data collection, and the method of data destruction after the completion of research.**

❏ Record in the personal computer with protection code

❏ Keep document / CD / files in the locked cabinet and only the researcher has a key to open or close

❏ Destroy the documents / CD / files after the research is complete

❏ Forward CD of patient’s history back to the Medical Statistics Division after the research is complete

 ❏ Keep document / CD / files for……….years after the research is complete

 ❏ Others, please specify ................................................................................................................................

 Please specify the persons who can access the information ………………………………………………...…….

*Principal investigator is responsible for maintaining the confidentially of the participant/volunteer informations and it must be stated in the participant information sheet.*

**Researcher’s statement**

1) All investigators will conduct the research based on the Researcher’s Code of Ethics, the ethical criteria of human research studies, in intention to maintain prestige and honor within the researchers and will use the IRB approved documents to obtain the informed consent from the participant/volunteer correctly with the respect to the dignity, right and welfare of the participant/volunteer significantly;

2) All investigators will inform the IRB committee to obtain approval before conducting protocol amendment or changes in the researcher team. In addition, if the project amendment affects the participant/ volunteer, we will inform and ask for the consent from the participant every time;

3) All investigators will report the serious/unexpected adverse event during conducting the research according to the IRB regulations within the course, and will provide assistance to solve the problems at the best of our ability;

4) All investigators have good knowledge and understanding in every step of the proposed research process, and are capable to solve the problems or adverse event which may occur during conducting the research in order to ensure the safety and welfare of participant/volunteer;

5) After the research is accomplished, we will summarize the operating procedures and submit the close-out report to the IRB regulations within the course. If the research may take over one year, we will submit the annual research progress report and document asking for COA extension, before the expiry date;

6) All investigators will not initiate the research study before the official approval of the Phyathai-Paolo Hospital Group Institutional Review Board;

7) All investigators understand that we will have access for data entry and management that is confidential. All personally identifying records developed or acquired in the course of the research study will be kept confidential and will not be disclosed by any person in possession of the record, nor will these records be discoverable by persons not involved in the research project.

Signature...................................................... (Principle Investigator)

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

Date……..….……..…………....….........

Signature...................................................... (Co-Investigator)

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

Date….…………………......……...........

Signature...................................................... (Co-Investigator)

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

Date ….………..............…....….........

*(Principle Investigator and all Co-Investigator must be signed and specified date in this research proposal)*

1. **Suggestion and approval from the Hospital Executive Director**

Signature......................................................

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

 *Position* …………………………………………………

Date ….………….................…....….....................