**Memorandum**

Department: ....................................................................................... Tel. .....................................

Ref No. ……………/.................... Date: .....................................................................

Subject: Proposal Submission for Retrospective Study / Case Report for Ethical Review in Human Research

To: Chairperson, Human Research Ethics Committee, Social and Behavioral Sciences, Prince of Songkla University

I, ......................................................................, affiliated with .........................................................,

would like to submit a research project titled (in Thai and English):…………………………….................

...............................................................................................for ethical review in human research. The supporting documents for consideration are attached as follows:

1. Proof of registration in the PRPM database (if available) 1 copy

2. Human Research Ethics Submission Form (AP-002) 3 copies

3. Full research protocol 3 copies

4. For Case report/series (< 5 cases): submission of 1 copy

final report is sufficient (protocol not required)

5. Curriculum vitae and relevant expertise of the researcher(s) 3 copies

(in Thai or English)

6. Certificate of human research ethics training 3 copies

(within the last 2 years) for all researchers

7. Research instruments, e.g., questionnaires, 3 copies

data collection forms (if applicable)

8. Other supporting documents (e.g., licenses, consent forms 3 copies

for photo usage, data access request letters,

facility use requests, etc.)

9. A single electronic file containing items 1–7 submitted to: 1 file

sbsirb.psuhatyai@gmail.com

Kindly consider the above for ethical approval.

|  |  |
| --- | --- |
| Signature…………………………………………… | Signature…………………………………………… |
|  (……………………………..…………….) |  (………………………………..…………….) |
| Advisor (if the PI is a student)Principal Investigator |  Principal Investigator |
| The affiliated institution has approved this research project.Signature: ………………………………….………….…………… |
|  (………………….………..……………..…………….)Position: ............................................................... |
| Head of Affiliated Unit |

**Submission Form for Ethical Review in Human Research**

**For Retrospective Study/Case Report**

1. Research Project Title (in Thai and English)

……………………………………………………………………………………………………………………………………………………………………………………………………….........................................................................................................................

2. Principal Investigator and Affiliated Institution (including Advisor's name if the PI is a student), in Thai and English:

3. Co-Investigators and Affiliated Institutions, in Thai and English:

4. Executive Summary (maximum two pages, A4):

• Objectives

• Source(s) of existing data, e.g., medical records, publicly accessible data sources. If external organizations are involved, attach documentation of data access approval from the relevant agency.

• Period for data collection

• Data elements to be used in the research (attach case record form at the end of the protocol)

• Sample size calculation to address research questions (if applicable)

• Data analysis plan, data presentation, and publication plans

• Data access procedures

• Data destruction plan

5. Ethical Considerations:

• Measures for safeguarding the confidentiality of participants during both the research process and the presentation of results

• Data storage and access levels. If medical records are used, only those involved in patient care or authorized research team members should access the data. Encryption must be used to restrict access to electronic files.

• No disclosure of identifiable information. If photographs of data owners must be presented, identifying features must be appropriately obscured, and written consent must be obtained before presentation.

• Intended use of the research results Certification:

I hereby certify that:

 The above information is true

 I fully understand the implications of the content

 I will adhere to the principles of human research ethics

|  |  |
| --- | --- |
| Signature: …………………..........…………….………… |  Signature: …………………….….....……………..…… |
|  (……………....………………..…………….) |  (…………………………………………..………) |
|  Advisor (if the PI is a student)  Principal Investigator |  Principal InvestigatorSignature.......................................................... (..........................................................)Co-InvestigatorSignature.......................................................... (...........................................................) Co-InvestigatorSignature.......................................................... (...........................................................) Co-Investigator |
| The affiliated institution has approved this research project. |
| Signature………………………………….………….…………… |
|  (…………………….……………………..…………….)Head of Affiliated Institution |