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| Please fill in this form and provide necessary documents for submission.  This form will facilitate and fasten the review process. | | | | | | **IRB No.** |
| **Section 1 : Protocol identification** | | | | | | **Remarks** |
| 1.1 | Protocol title (ไทย) | | | | |  |
| 1.2 | Protocol title (English) | | | | |  |
| **Section 2: Investigator** | | | | | |  |
|  | Name | Degree/Specialty | GCP training certificate  Expired date | Institutional  affiliation | Contact phone /email |  |
| PI |  |  | 17 February 2024 |  |  |
| Co-PI | Krissana Panrong |  |  |  |  |
| **Section 3 : Protocol information** | | | | | |  |
| 3.1 | Number of cases (not more than 3) | | | | |  |
| 3.2 | Has the source of data/information/chart originated from your own department or unit? c Yes c No | | | | |  |
| 3.3 | Do you record any HIPAA identifiers e.g., names, social security number, addresses, telephone number, etc.? c Yes c No  If “Yes”: Explain why it is necessary to record findings with identifiers?  Describe the provisions you have taken to maintain confidentiality of data:  …………………………………………………………………………………………………………………………………………………………………………….............  …………………………………………………………………………………………………………………………………………………………………………….............  ……………………………………………………………………………………………………………………………………………………………………………............. | | | | |  |
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| Investigator signature ……………........................….….....................................................................................dated…….....…..…/…….....…..…/…….....…..…  (Please retain copy of the completed form for your study record.) | | | | | | |
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| **Section 4 : Assessment by Med Chula IRB** | | | | | |  |
| **Descriptive summary of the protocol :** | | | | | |  |
| **Justification for using exemption process:** c **Yes** c **No** | | | | | |  |
| **Suggestion/Recommendation :**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | |  |

**c I declare that I have no conflict of interest in this protocol.**

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| --- | --- | --- |
| **Reviewer’s Signature** |  | **Date** .........../.........../........... |
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| **Section 5 : Step in submitting documents to Med Chula IRB** | |  |
| 5.1 | Letter to Head of the Department acknowledging the submission of case report for review by Med Chula IRB | 1 copy |
| 5.2 | Submission and Assessment form for Case Report | 1 copy |
| 5.3 | Manuscript of case report (ready for printing) | 1 copy |

**HIPAA identifiers that must be removed to make health information de-identified**

The following identifiers of the individual or of relatives, employers or household members of the individual must be removed:

1. Names
2. Address (including zip code)
3. Dates (birth, admission, discharge, death)
4. Telephone numbers
5. Fax numbers
6. E-mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/License numbers
12. Vehicle identifiers and serial numbers (including license plate)
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) addresses
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code.

Reference: http://hipaa.bsd.uchicago.edu/background.html