受試者知情同意過程紀錄格式(貼於電子病歷)

※ 使用說明：

- 受試者參與臨床研究案，若屬若涉及病人照護、診斷或治療之介入性計畫，其取得同意者、獲得知情同意者姓名、取得時間、取得方式應記錄於病歷。另須於病歷紀錄已提供受試者「臺大醫院臨床試驗/研究參與者須知」，以及“知情同意”決定過程、提供訊息者和獲得知情同意者姓名及日期。為利計畫人員執行，提供二種受試者知情同意過程記錄格式如下，格式一用於受試者接受充分說明後即簽署同意書；格式二用於受試者接受充分說明後，尚須帶回同意書考慮是否參加，之後再簽署同意書，故分開兩張張貼。
- 請選擇適用之格式或自行設計(但應有格式內之內容)，並將「知情同意過程記錄格式」內容紀錄於電子病歷中(可記載於門診、急診、住院等 SOAP 或相關表單中)
- 格式內之文件編號為本格式版本，請勿更動。

格式一（說明及同意書簽署同時進行）

NTUH-REC No.:_____

Study Title：_____

_____

_____

The subject_____ has been provided the sheet of Clinical Trial/Research Note and was fully explained the content of the informed consent form on____/__/____ (yyyy/mm/dd) by □Principle Investigator □Co-Investigator □Other:

(identity)_____:(name)_____. The subject had enough time to consider and ask all questions regarding the study.

The subject had signed informed consent form on ____/____/____(yyyy/mm/dd). A copy of the signed informed consent form was provided to the subject.

Principal Investigator\Co-Investigator：_____

____/____/____(yyyy/mm/dd)

文件編號	01010-4-000001	版次	05

(格式二請見次頁)

格式二（說明及同意書簽署分階段進行）

(1)說明階段

NTUH-REC No.:_____

Study Title：_____

_____

_____

The subject_____ has been provided the sheet of Clinical Trial/Research Note and was fully explained the content of the informed consent form on____/__/____(yyyy/mm/dd) by □Principle Investigator □Co-Investigator □Other: (identity)_____:(name)_____.
The subject had enough time to ask all questions regarding the study. The subject brought the consent form back to consider whether to participate.

Principal Investigator\Co-Investigator：_____

____/____/___(yyyy/mm/dd)

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(2)簽署同意書階段

NTUH-REC No.:_____

Study Title：_____

_____

_____

The subject_____ understood the content of the informed consent form and signed informed consent form on ____/__/__(yyyy/mm/dd). A copy of the signed informed consent form was provided to the subject.

Principal Investigator\Co-Investigator：_____

____/____/___(yyyy/mm/dd)

文件編號	01010-4-000003	版次	05