CHONG HUA HOSPITAL
Healing with Passion. Caring with Compassion.

PROTOCOL AMENDMENT SUBMISSION FORM

Form HRP-IRB-017

Any amendment to an approved protocol must be reviewed and approved by the IRB before the amendment is implemented. Such amendments could include changes to the study design, procedures, enrollment, methods of recruitment, personnel, funding source or the consent form/information sheet. This includes changes that appear to reduce risks to subjects. There are NO EXCEPTIONS to this rule.

Principal Investigator:	Date:
Sub-Investigators:	Correspondent:

Protocol No. and Study Title:

1. Using the standard template attached describe each proposed amendment and provide the reason for such.

2. For each amendment listed above, explain whether the proposed amendment increases or decreases the level risk to participants (thereby changing the risk/benefit ratio) and, if so, describe.

☐ Does not change the risk/benefit ratio

☐ Increase the risk to participants

_____

☐ Decrease the risk to participants

3. Has the funding source or the status of funding changed since initial or last re-approval review?

☐ YES ☐ NO

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TYPE OF AMENDMENT REQUESTED:

☐ EXPEDITED (Minor changes)

☐ FULL REVIEW BY IEC/IRB (More than minor changes or that amendment "materially affects risks to subjects")

SIGNATURE:

_____ Date: _____
Principal Investigator

COMMENTS: ☐ EXPEDITED (Minor changes) ☐ FULL REVIEWED

APPROVAL:

_____ Date: _____
Chairperson, IEC/IRB

COMPLETION:

_____ Date: _____
Secretary, IEC/IRB

PROTOCOL NUMBER: IRB - ☐☐☐☐ - ☐☐