(八) Protocol Synopsis

I. Protocol title:

II. Objectives:

III. Test drug:

1. Name:
2. Dosage form:
3. Dose(s):
4. Dosing schedule:
5. Mechanism of action (if known):
6. Pharmacological category:

IV. Developmental phase: phase □I □II □III □IV □Others

V. Study design:

1. □Control: □placebo
□active (please specify name and dosage)
□other
□Uncontrolled

2. Blinding: □open-label □evaluator blind □single blind □double blind
□double dummy □other

3. Randomized: □yes □no

4. □Parallel □Cross-over □Other

5. Duration of treatment: days weeks months years

6. Titration: □forced □optional □none

7. □Multi-national □Multi-center(Taiwan) □Single center

VI. Endpoints:

1. Primary endpoint(s):

2. Secondary endpoints:

VII. Selection criteria:

1. Main inclusion criteria:

2. Main exclusion criteria:

VIII. Study procedures:

IX. Concomitant treatment:

1. Permitted:

2. Prohibited:

X. Statistics

1. Primary hypothesis: □superiority □non-inferiority
□equivalence □other

2. Sample size: enrolled
evaluable

3. Efficacy population: □ITT □PP □other
Safety population: □ITT □PP □other

4. Statistical method(s) for efficacy/safety evaluations:

5. Planned interim analysis: □yes □no

XI. Please attach flow chart and/or assessment schedule, if available.