Abbreviated Title:
Version Date:

Title Page:

（說明：可自行編輯，但一般包含以下項目）

Title:

Principal Investigator:

Co-investigators or sub-investigators:

（說明：若為本院主導之多中心臨床試驗，請列出參與之醫院及該院之 **principal investigator** 。）

Synopsis

（說明：可自行編輯，但一般包含以下項目）

Title:	
Objectives	
Eligibility:	*Include the most significant criteria for patient selection such as age, diagnosis, disease status (stage, prognostic group), prior therapy, exceptions to normal organ function*
Design of trial	*Phase of trial, design of the trial, dose/schedule of drugs for each arm, randomization*
Study treatment:	*Include the investigational product and comparator product (dosing schedule, administration route, ….)*
Primary endpoint	
Statistical analysis and sample size estimation	*Planned statistical analysis for primary endpoint, number of patients to be enrolled*

Table of Contents (說明：請視個別計畫特性與內容修改)

1. INTRODUCTION

1.1 BACKGROUND AND RATIONALE:

1.2 STUDY OBJECTIVES

1.2.1 Primary Objective:

1.2.2 Secondary Objective(s):

2 ELIGIBILITY ASSESSMENT AND ENROLLMENT

2.1 ELIGIBILITY CRITERIA

2.1.1 Inclusion Criteria

2.1.2 Exclusion Criteria

2.2 SCREENING EVALUATION

2.3 REGISTRATION PROCEDURES (APPLICABLE FOR MULTISITE TRIALS)

2.4 RANDOMIZATION (OR STRATIFICATION) PROCEDURES (APPLICABLE FOR RANDOMIZED CONTROLLED TRIALS)

2.5 BASELINE EVALUATION

3 STUDY IMPLEMENTATION

3.1 STUDY DESIGN

3.2 DRUG ADMINISTRATION

3.3 DOSE MODIFICATIONS

3.4 QUESTIONNAIRES (IF APPLICABLE)

3.5 STUDY CALENDAR

Sample Calendar:

Procedure	***Screening/ Baseline***	***Cycle 1***					***Subsequent Cycles***			***Post Therapy Follow-up***
		Day X	***Day X***	***Day X***	***Day X***	***Day X***	***Day X***	***Day X***	***Day X***	
History and PE										
Vital signs										
Performance Score										
Labs (list specific labs)										
Biopsies										
Correlative Research Studies										
PK/PD										
Radiological Assessments (list specific studies)										
Other Specific Assessments (such as EKG/ECHO, Audiology, PFT)										
Response Evaluation[1]										
Adverse Events		*X*	→	→	→	→	→	→	→	
Concomitant Medications		*X*	→	→	→	→	→	→	→	

Use footnotes as appropriate (e.g., [1] *response assessment to be done every other cycle)*

3.6 COMPENSATION (IF APPLICABLE)

3.7 CRITERIA FOR REMOVAL FROM PROTOCOL THERAPY AND OFF STUDY CRITERIA

3.7.1 Criteria for removal from protocol therapy

3.7.2 Off-Study Criteria

4 CONCOMITANT MEDICATIONS/MEASURES

5 BIOSPECIMEN COLLECTION

5.1 CORRELATIVE STUDIES FOR RESEARCH/PHARMACOKINETIC STUDIES (IF APPLCABLE)

5.2 SAMPLE STORAGE, TRACKING AND DISPOSITION

5.3 SAMPLES FOR GENETIC/GENOMIC ANALYSIS (IF APPLICABLE)

5.3.1 Description of the scope of genetic/genomic analysis

5.3.2 Description of how privacy and confidentiality of medical information/biological specimens will be maximized.

5.3.3 Management of Results

5.3.4 Genetic counseling

6 DATA COLLECTION AND EVALUATION

6.1 DATA COLLECTION

6.2 CRITERIA OF ENDPOINTS

6.3 TOXICITY CRITERIA

7 SAFETY REPORTING REQUIREMENTS/DATA AND SAFETY MONITORING PLAN

7.1 DEFINITIONS

7.1.1 Adverse Event

An adverse event is defined as any reaction, side effect, or untoward event that occurs during the course of the clinical trial associated with the use of a drug in humans, whether or not the event is considered related to the treatment or clinically significant.

(Please describe how to manage AEs in this study, such as report..record…)

7.1.2 Suspected adverse reaction

Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, 'reasonable possibility' means there is evidence to suggest a causal relationship between the drug and the adverse event. A suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any adverse event caused by a drug.

7.1.3 Unexpected adverse reaction

An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application. "Unexpected", also refers to adverse events or suspected adverse reactions that are mentioned in the investigator brochure as occurring with a class of drugs or as anticipated from the pharmacological properties of the drug, but are not specifically mentioned as occurring with the particular drug under investigation.

7.1.4 Serious

An adverse event or suspected adverse reaction is considered serious if in the view of the investigator or the sponsor, it results in any of the following:

- Death,
- A life-threatening adverse drug experience
- Inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect.
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

7.1.5 Disability

A substantial disruption of a person's ability to conduct normal life functions.

7.1.6 Life-threatening adverse drug experience

Any adverse event or suspected adverse reaction that places the patient or subject, in the view of the investigator or sponsor, at immediate risk of death from the reaction as it occurred, i.e.,

it does not include a reaction that had it occurred in a more severe form, might have caused death.

7.1.7 Unanticipated Problem

Any incident, experience, or outcome that:

- Is unexpected in terms of nature, severity, or frequency in relation to

  (a) the research risks that are described in the IRB-approved research protocol and informed consent document; Investigator's Brochure or other study documents, and

  (b) the characteristics of the subject population being studied; **AND**
- Is related or possibly related to participation in the research; **AND**
- Places subjects or others at a g*reater risk of harm* (including physical, psychological, economic, or social harm) than was previously known or recognized.

7.2 REC OR IRB REPORTING

Please describe the reporting principles for above safety items (when, how, timeframe).

If this is a multi-center trial, please describe the reporting requirements

7.3 DATA AND SAFETY MONITORING PLAN

(可參考以下寫法，並依計劃性質做修改)

7.3.1 Principal Investigator/Research Team

All protocols should include a DSM plan which describes how the investigator plans to oversee research subject safety and ensure data integrity. The PI and his/her research staff are part of the monitoring plan but may not be the only ones conducting monitoring activities for any given protocol.

The clinical research team will meet on a regular basis {*insert frequency*} when patients are being actively treated on the trial to discuss each patient. Decisions about dose level enrollment and dose escalation if applicable will be made based on the toxicity data from prior patients.

All data will be collected in a timely manner and reviewed by the principal investigator or a lead associate investigator. Adverse events will be reported as required above. Any safety concerns, new information that might affect either the ethical and or scientific conduct of the

trial, or protocol deviations and violations will be immediately reported to the IRB using iRIS and if applicable to the Sponsor.

The principal investigator will review adverse event and response data on each patient to ensure safety and data accuracy. The principal investigator will personally conduct or supervise the investigation and provide appropriate delegation of responsibilities to other members of the research staff.

7.3.2 Sponsor Monitoring Plan (If this is a sponsor-initiated trial).

7.3.3 Data Safety Monitoring Board (DSMB) (if applicable)

A DSMB is an impartial group established to oversee a clinical trial and review the results to determine if they are acceptable. Members of a DSMB must be multidisciplinary and include members with relevant clinical and statistical expertise. The DSMB should meet at least annually or more often depending on the activity and nature of the clinical trial being monitored.

This protocol requires monitoring by the Data Safety Monitoring Board (DSMB) as described above in Section X.X. [*insert appropriate statistical considerations section/subsection number here]*. Interim outcome results will not be revealed to the investigators of the trial; results will be presented to the investigators prior to final accrual to the trial only if the DSMB recommends early termination of the trial. (NOTE: the study statistician is responsible for providing the description of how the monitoring will take place, including endpoints to be monitored and the frequency or timing of monitoring.)

8 STATISTICAL SECTION

- *Include a statement on racial/ethnic and gender make-up of the study population.*
- *Provide a justification for excluding any group (e.g., age, gender or race).*
- *Restate **objectives** and define study **endpoints** being measured and clearly delineate **statistical methods.***
- *Clearly delineate how the **sample size** (accrual limit) was determined.*

(可參考以下寫法，並依計劃性質做修改)

For phase I studies, cohorts of 3 patients are used for each dose level. The dose level on which 2 patients experience unacceptable toxicity is usually considered the DLT. The next lower dose level on which no more than 1/6 patients experience unacceptable toxicity is usually considered the MTD.

For phase II studies, 30 patients are usually employed to define response. An early stopping rule may be used to terminate the study if the agent under study is clearly inactive (e.g., 0 of 9 or 0 of 14 objective responses).

For phase III comparative trials, the number of patients per arm is derived from the expected response rates or other outcome measures, the difference to be detected, and the power to detect the difference. Background data supporting the predicted response rates and expected difference should be included. Identify the desired -difference to be detected, level of significance (), power of the study (1-) and sample size.

9 COLLABORATIVE AGREEMENTS (IF APPLICABLE)

9.1 MULTI-INSTITUTIONAL GUIDELINES

9.1.1 IRB Approvals

9.1.2 Amendments and Consents

10 PHARMACEUTICAL AND INVESTIGATIONAL DEVICE INFORMATION

*For **each** study drug, describe:*

10.1 DRUG X

10.1.1 Source:

10.1.2 Toxicity:

10.1.3 Formulation and preparation:

10.1.4 Stability and Storage:

10.1.5 Administration procedures:

10.1.6 Incompatibilities :

11 REFERENCES

Include relevant, current key references for proposed study.

12 APPENDIX (IF ANY)