I. INTRODUCTION AND PURPOSE

A clinical protocol that meets scientific and ethical standards is a fundamental requirement of clinical investigations. The site must determine the scientific, ethical and financial merits of conducting the study. The sponsor must compensate the site for the resources necessary to perform all study-related procedures according to the requirements of good clinical practice (GCP). This standard operating procedure (SOP) describes the steps for fulfilling the regulatory, medical, and ethical requirements for assessing the feasibility of implementing a protocol at this investigative site.

2. SCOPE

This SOP applies to the activities involved in assessing protocols for studies conducted at this investigative site subject to investigational new drug (IND) regulations for drugs and biologics during all investigational phases of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

<table>
<thead>
<tr>
<th>CFR Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 CFR 56.109</td>
<td>IRB review of research</td>
</tr>
<tr>
<td>21 CFR 56.111</td>
<td>Criteria for IRB approval of research</td>
</tr>
<tr>
<td>21 CFR 312.21</td>
<td>Phases of an investigation</td>
</tr>
<tr>
<td>21 CFR 312.23</td>
<td>IND content and format</td>
</tr>
<tr>
<td>21 CFR 312.60</td>
<td>General responsibilities of investigators</td>
</tr>
</tbody>
</table>

May 1997 International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline

4. REFERENCES TO OTHER APPLICABLE SOPs

<table>
<thead>
<tr>
<th>SOP Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GA-102</td>
<td>Responsibilities of the Research Team</td>
</tr>
<tr>
<td>PM-301</td>
<td>Site-Sponsor/CRO Communications</td>
</tr>
</tbody>
</table>
5. ATTACHMENTS

A. Protocol Assessment Checklist
B. Subject Expenses Worksheet
C. Employee Salary Expenses Worksheet
D. Budget Worksheet

6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in conducting clinical trials at this research site. This includes the following:

- Principal investigator
- Subinvestigator
- Research manager
- Research nurse/coordinator
- Data manager
- Support staff

7. DEFINITIONS

The following definitions from the International Conference on Harmonisation, Good Clinical Practice: Consolidated Guideline apply to this SOP.

**Protocol:** A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline, the term protocol refers to protocol and protocol amendments.

**Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

**Investigational Product:** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

**Well-being (of the trial subjects):** The physical and mental integrity of the subjects participating in a clinical trial.
8. PROCESS OVERVIEW

A. Based upon the established review process, evaluate the feasibility of carrying out the protocol at this investigative site.

9. PROCEDURES

A. Evaluate the protocol and the investigational article, assess the potential impact upon subjects, and review the budget.

<table>
<thead>
<tr>
<th>Identify which clinical research team members are responsible:</th>
<th>Describe how your site implements this:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• PI</td>
<td>Based upon the established review process, determine the scientific, ethical and financial merits of conducting the study at this investigational site.</td>
</tr>
<tr>
<td>• Subinvestigators</td>
<td>Distribute the protocol and assessment tools to key research team members for their assessment (Attachment A, Protocol Assessment Checklist and Attachments B, C and D for budget calculations).</td>
</tr>
<tr>
<td>• Research manager</td>
<td></td>
</tr>
<tr>
<td>• Research nurse/coordinator</td>
<td></td>
</tr>
<tr>
<td>• PI</td>
<td>Review comments from research team and determine feasibility.</td>
</tr>
<tr>
<td>• Subinvestigator</td>
<td><em>(Insert here how your site does this, e.g., meeting, e-mail, memo.)</em></td>
</tr>
<tr>
<td>• Research manager</td>
<td></td>
</tr>
<tr>
<td>• Research nurse/coordinator</td>
<td></td>
</tr>
<tr>
<td>• Research manager</td>
<td>Notify the sponsor of the site’s decision.</td>
</tr>
<tr>
<td>• Research nurse/coordinator</td>
<td></td>
</tr>
</tbody>
</table>
## PROTOCOL ASSESSMENT CHECKLIST

**Protocol title:**

**Study article(s):**

**Phase:**

### 1. General

Is the number of patients to be enrolled realistic for this site?  
☐ Yes  ☐ No

Is the enrollment period realistic for this site?  
☐ Yes  ☐ No

Are the inclusion/exclusion criteria too restrictive?  
☐ Yes  ☐ No

Will our IRB have problems with any aspects of this protocol?  
☐ Yes  ☐ No

**Comments:**

- 
- 
- 
- 
- 
- 
- 
- 
- 

### 2. Procedures/clinical assessments

Are frequent observations/procedures required?  
☐ Yes  ☐ No
Is the visit schedule flexible?  
☐ Yes  ☐ No

Are there multiple follow-up visits required?  
☐ Yes  ☐ No

Are procedures/clinical assessments difficult?  
☐ Yes  ☐ No

Is additional staffing/specialist involvement needed?  
☐ Yes  ☐ No

Comments: ____________________________________________________________
_______________________________________
_______________________________________
_______________________________________
_______________________________________
_______________________________________
_______________________________________
3. Study population

Subject health status

Acute and life-threatening ☐ Yes ☐ No

or
Chronic and life-threatening ☐ Yes ☐ No

or
Healthy ☐ Yes ☐ No

Subject population

Adults capable of giving consent ☐ Yes ☐ No

Impaired adults ☐ Yes ☐ No

Minors ☐ Yes ☐ No

Comments: ____________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

4. Case report forms

Is concomitant medication documentation detailed?
☐ Yes ☐ No

Is adverse event documentation complex?
☐ Yes ☐ No

Are diaries detailed?
☐ Yes ☐ No

Do the diaries need to be transcribed?
☐ Yes ☐ No
Is the study article dispensing/accountability complicated?  
☐ Yes
☐ No

Comments: ________________________________________________________________

______________________________________________________________

______________________________________________________________

______________________________________________________________

_______________________________
5. Other considerations

Will our patient population benefit from the study?

☐ Yes  ☐ No

Is this study desirable to do from a scientific standpoint?

☐ Yes  ☐ No

Comments:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Do you recommend that the study be conducted at this site?

☐ Yes  ☐ No

Comments:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

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