Site 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 realistic? ◯ Yes ◯ No

Do you foresee problems with any aspects of the protocol with regards to the review by the IRB/IEC? ◯ Yes ◯ No

Comments:

_____

_____

2. Procedures/Clinical Assessments

Are frequent observations/procedures required? ◯ Yes ◯ No

Is the visit schedule flexible? ◯ Yes ◯ No

Are multiple follow-up visits required? ◯ Yes ◯ No

Are procedures/clinical assessments different from normal day-to-day practice? ◯ Yes ◯ No

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

Comments:

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3. Study Population

Subject health status

Acute and life-threatening ◯ Yes ◯ No
Chronic and life-threatening ◯ Yes ◯ No
Healthy ◯ Yes ◯ No

Subject population

Adults capable of giving consent ◯ Yes ◯ No
Mentally impaired adults ◯ Yes ◯ No
Minors ◯ Yes ◯ No

Comments:

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_____

4. Case Report Forms

Is adverse event documentation complex? ◯ Yes ◯ No

Is concomitant medication documentation detailed? ◯ Yes ◯ No

Does the protocol require subjects to keep a diary? ◯ Yes ◯ No

Are diaries detailed? ◯ Yes ◯ No

Do the diaries need to be transcribed? ◯ Yes ◯ No

Is the investigational product dispensing/accountability complicated? ◯ Yes ◯ No

Comments:

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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:

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Signature _____ Date ____/____/____