

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 | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <i>or</i> | | |
| Chronic and life-threatening | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <i>or</i> | | |
| Healthy | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Subject population

- | | | |
|----------------------------------|------------------------------|-----------------------------|
| Adults capable of giving consent | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Impaired adults | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Minors | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Comments: _____

4. Case report forms

- | | | |
|---|------------------------------|-----------------------------|
| Is concomitant medication documentation detailed? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Is adverse event documentation complex? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Are diaries detailed? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do the diaries need to be transcribed? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Is the study article dispensing/accountability complicated? | <input type="checkbox"/> Yes | <input type="checkbox"/> 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: _____

How can the Office of Clinical Trials help you?

Call 2-5245