PROTOCOL FEASIBILITY ASSESSMENT CHECKLIST

Protocol Title: _____

Study Article(s): _____ **Phase:** _____

Therapeutic Area (Disease): _____

1. General

Does the protocol meet the research site's area of expertise? ❑ Yes ❑ No
Is the number of patients to be enrolled realistic for this site? ❑ Yes ❑ No
Number of subjects to be recruited by research site _____
Are the preparation time lines for this protocol realistic? ❑ Yes ❑ No
Is the enrolment period realistic for this site? ❑ Yes ❑ No
Do the inclusion/exclusion criteria fit with research site patient population? ❑ Yes ❑ No
Will we have to recruit subjects from outside? ❑ Yes ❑ No
Comments: _____

_____

_____

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
Comments: _____

_____

Is the visit schedule flexible? ☐Yes ❑ No
Comments: _____

_____

_____

Are there multiple follow-up visits required? ❑ Yes ❑ No
Are procedures/clinical assessments difficult? ❑ Yes ❑ No
If yes, describe: _____

_____

_____

Estimated monitoring visit schedule time requirements: _____
Frequency of visits: _____
Estimated total number of visits: _____
Can we hand the volume of visits in the current research site schedule? ❑ Yes ❑ No
Other considerations of this protocol that might be a time/staffing factor: _____

_____

_____

Current staff available for this protocol:
Principal Investigator: _____

Study Coordinator: _____

Lab technician: _____

Other Staff required: _____

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

Comments: _____

_____

_____

1. **Study population**
   - Adults capable of giving consent ❑ Yes ❑ No
   - Adults but consent process compromised ❑ Yes ❑ No
   - Geriatric adults ❑ Yes ❑ No
   - Minors ❑ Yes ❑ No

Comments: _____

_____

_____

4. Case report forms (if CRF available)

How many pages is the CRF? _____

Is con medication documentation detailed and or repetitive?	❑ 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 the research site? ❑ Yes ❑ No

Comments: _____

_____

_____

_____

_____ _____/_____/_____

Signature Date