

Research Study Feasibility Review Checklist

Name of Study: _____

Sponsor: _____

Dept: _____

Who will be the Principal Investigator (PI)? _____

Who are planned to be the Sub-Investigators? _____

Investigator Questions

Does this trial investigate a new drug or device? (i.e. IND/IDE)

Yes or No (circle one)

Comments:

Projected enrollment? (In general, 10 patients must be enrolled to break even)

Comments:

How many patients will need to be screened for projected enrollment?

Comments:

Are there adequate number of patients to enroll as projected?

Yes or No (circle one)

Comments:

Is there a competing trial that would prevent enrollment of those patients?

Yes or No (circle one)

Comments:

Investigator & Research Supervisor Questions

Is there adequate Research Nurse/Coordinator support?

Intended Coordinator: _____

Yes or No (circle one)

Comments:

Do budget numbers appear adequate, recognizing full contract may not be available?

Yes or No (circle one)

(Projections should be reviewed w/ Financial Administrator)

Comments:

Are the sponsor's enrollment timelines adequate? (i.e., after activation is there enough time to enroll)

Yes or No (circle one)

Comments:

Approvals: *By signing below I acknowledge that I have carefully read, reviewed and understand the contents of this document.*

Principal Investigator

Date

Research Nurse Supervisor

Date

Research Manager

Date

Financial Administrator

Date