## UAB Abbreviated Protocol Feasibility Assessment Form

**Protocol Title:** ______________________________

**Protocol Number:** ______________________________

**PI:** ____________________________________________

**Protocol Phase:**
- □ Phase I
- □ Phase II
- □ Phase III
- □ Phase IV
- □ Device
- □ Other

**Sponsor/CRO:** __________________________________

**Protocol Article:** __________________________________

**Drug Administration:**
- □ N/A
- □ PO
- □ SQ
- □ IM
- □ IV

**Other Critical Descriptor:** ____________________________

## POPULATION:
1. What is the population age? __________________________
2. What is the participant health status?
   - □ life threatening
   - □ chronic
   - □ healthy
3. What type of treatment population is required? ________________
4. What is the number of participants expected to enroll? __________________________
5. Is the number of participants to be enrolled at this site realistic? □ Yes □ No
6. Do we have access to the participant population? □ Yes □ No
7. Are the inclusion/exclusion too restrictive? □ Yes □ No
   - * Seasonal issues? □ Yes □ No
   - * Concerns with inclusion/exclusion? □ Yes □ No
8. Is this study for Clinical Reasons or Academic? __________________________
9. Will participants need to be recruited from outside sources? □ Yes □ No
10. Will enrollment compete with other studies? □ Yes □ No
11. Do you expect significant adverse Events (AEs/SAEs)? □ Yes □ No

**Comments:** __________________________________________
_________________________😏____________________________
________________________________________________________________________
**PROTOCOL**

1. Is the protocol complex with multiple arms? □ Yes □ No
2. Is the protocol ethical? □ Yes □ No
3. Do you foresee the IRB having problems with the protocol? □ Yes □ No
4. Do you foresee any participant compliance issues? □ Yes □ No
5. Will coordination with other departments/services be required? □ Yes □ No
6. What departments/services? □ Lab □ Radiology □ Pharmacy □ Pathology □ CCTS: □ CRU □ CRSP □ Bionutrition □ Biospecimen □ Other________
7. Clinical Billables? □ Yes □ No
8. Duration of study? □ Yes □ No
9. Inpatient, outpatient or both? □ Inpatient □ Outpatient □ Both
10. Do the visits seem complex and time consuming? □ Yes □ No
11. Is the dosing schedule complex? □ Yes □ No

Comments:________________________________________________________________________________
_________________________________________________________________________________________

**PROCEDURES**

1. Are the procedures/clinical assessments complex? □ Yes □ No
2. Is there a washout period? □ Yes □ No
3. What procedures will be performed?

_______________________________________________________________________________________
_________________________________________________________________________________________
_______________________________________________________________________________________

4. Does the study collect PK samples? □ Yes □ No
5. Does the study require time intensive PK sampling? □ Yes □ No
6. Is special equipment required for the study? □ Yes □ No
STAFF

1. Is the workload manageable? □Yes □No
2. Is additional training necessary? □Yes □No
3. What training? □Start up, □diaries, □electronic devices? □Investigator meeting?
□Other_________________________________________________
4. Adequate staff to conduct the study? □Yes □No
5. Will the study require extended work hours, on call time, weekends? □Yes □No
6. Additional specialists/consults needed? □Yes □No
7. Will budget cover expenses? □Yes □No

Time Estimates (How many hours of your time do you estimate for the items below?)

1. Recruitment? *Please also complete Recruitment and Retention Form______________________________
2. Conducting visits (all visits)? ________________________________
3. Monitor visits? ____________________________________________
4. Addressing queries? _________________________________________
5. Entering data?
6. Source docs?
7. EDC? _____________________________________________
8. Scheduling visits & procedures? ________________________________
9. Will it be convenient or will pts miss work and school? _______________________
10. Managing adverse events? ________________________________

Comments about time requirements?
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
Experience with Sponsor/CRO? □Yes □No
Comments about sponsor/CRO__________________________________________________________
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RECOMMENDATION:

Pursue protocol □ Yes □ No

Pursue with conditions (explain below) □ Yes □ No

Do not pursue (explain below) □ Yes □ No

Comments:_______________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________

COMPLETED BY:______________________________________________________________

PI SIGNATURE:______________________________________________________________

DATE: ____________________________________________________________