CCTS
Center for Clinical and Translational Science
Clinical Research Support Program

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:_____
_____
_____
_____

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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

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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: _____