

# Comprehensive Protocol Feasibility Questionnaire

**Protocol Title:**  
**Potential Principal Investigator:**  
**Regulatory Coordinators:**  
**Department Chair:**

## PROJECT FEASIBILITY

PI and Study Team: YOUR RESPONSES TO THIS SURVEY CONSTITUTE A BEST ESTIMATE OF RESOURCES AND YOUR DESIRE AND CAPABILITY TO PARTICIPATE IN COMPLIANCE WITH PROTOCOL REQUIREMENTS

Study team is to complete the form after reviewing the synopsis, protocol, budget, and other sponsor materials.

Item	Yes	No	NA	UNK	Comments
<b>I. Impact (Section completed by PI)</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
1. Are the alternative treatments available for this patient population?					
2. Is there a clinical impact on patient treatment or need for therapy?					
3. Is there an impact on our reputation or academic interest in our specialty related to this research?					Is the impact positive or negative?

# Comprehensive Protocol Feasibility Questionnaire

Item	Yes	No	NA	UNK	Comments
<b>II. Protocol (Section completed by PI and Clinical team)</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
1. Does the protocol (i.e. objectives, procedures and safety considerations) agree with your clinical and ethical judgment for patient treatments?					
2. Is this study similar to previous studies conducted at our site?					
* If so, were the previous studies successful?					
3. Can the protocol be adequately integrated with routine standards of care?					
* Are there any comparators, placebo/marketed product used differently than standard of care?					
4. Is specialized equipment required?					<i>If yes, comment on availability (e.g., obtain from other departments or sponsor, or must be purchased, etc.)</i>
5. Are non-CCRC personnel required to conduct special procedures or efficacy measures?					<i>If yes, identify sub-specialist physicians, technicians, physical therapists, etc.).</i>
* Will special procedures requires evaluations or testing outside of regular clinic hours?					
6. Are frequent and severe AE's expected?					<i>If yes, comment on a clinical implications and note resource effects in section IV, q2.</i>
7. In which facility should this study be done?					
8. Which hospital departments should be involved? Who is the contact?					
9. Could subject compliance be an issue?					<i>Will time consuming measures be needed for compliance such as phone calls and postcards?</i>
10. Will drug be available at the end of the study for continued treatment of the patient?					<i>If so, is there a "patient assistance program" to help with drug costs after the research?</i>

# Comprehensive Protocol Feasibility Questionnaire

Item	Yes	No	NA	UNK	Comments
<b>III. Enrollment (Section completed by PI and Clinical team)</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
1. Are the inclusion/exclusion criteria reasonable to meet enrollment? List the disallowed meds here.					
2. Will these factors impede enrollment:					Comment on whether factors will discourage consent from parent or child.
* Washout period ?					
* Age ?					
* Duration of participation ?					
* Frequency of visits ?					
* Frequency of dosing ?					
* Procedural discomfort ?					
* Other medical conditions ?					
* Medication restrictions ?					
3. Estimate expected enrollment:					
* Total number of subjects					
* No. of subjects/month					
* Ratio of screen to failure					
4. What is the source of patients ? Ex: clinic, preadmission testing, inpatient)					
5. Will the sponsor provide resources and/or a plan of action for recruitment?					If yes, comment.
6. Based on past/current knowledge of patient population, how many potential patients would be expected ?					
7. How many can be enrolled based on estimates and review ?					

# Comprehensive Protocol Feasibility Questionnaire

Item	Yes	No	NA	UNK	Comments
<b>IV. Procedures (Section completed by PI and Clinical team)</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
1. Are there frequent diagnostic procedures that may cause scheduling issues ?					
2. Are any procedures difficult for the patient population to tolerate ?					
3. Are any of the procedures that are non-standard of care painful ?					
4. If this is a drug study, is the dosing scheduling complex ?					This will take extra staff time for education of patients, pharmacy, floor nurses, etc.
5. Are any of the procedures inconvenient causing subjects to miss work/school or lengthy scheduling ?					Increases dropout risk.
6. If diaries are used, is transcription by research staff necessary ?					This takes staff time and increases error risk.
7. Will this study require substantive patient education on procedures ?					
8. Should subjects be reimbursed for participation ?					
<b>V. Sponsor Expectations (Section completed by Clinical team and OCRSS Regulatory Coordinator)</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
1. Is the sponsor expected timing reasonable to enroll the number of patients expected ? (See OCRSS Sponsor Feasibility Questionnaire)					
2. Can we enroll the number of subjects that the sponsor expects ?					
3. Are the visit schedule and times acceptable for subjects and practical for study personnel ?					

# Comprehensive Protocol Feasibility Questionnaire

Item	Yes	No	NA	UNK	Comments
<b>VI. Sponsor/CRO (Section completed by OCRSS Regulatory Coordinator)</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
1. Do you have previous experience with the CRO/sponsor ?					If yes, comment on +/- experiences.
2. What is duration of project ?					If yes, comment on +/- experiences.
3. Are there other considerations, which would increase complexity of paperwork ?					
4. Is the IRB likely to approve protocol ?					
<b>VII. Resources (Section completed by Clinical team and OCRSS Regulatory Coordinator)</b>					<input type="checkbox"/> Recommended <input checked="" type="checkbox"/> Not Recommended <small>Financial</small> <small>should reflect extra resource requirements.</small>
1. Will extended staff hours be required ?					Comment on after-hour or weekend requirements for CCRC staff.
2. Is current staffing adequate to conduct the trial ?					If no, comment on whether overtime and/or additional staff will be necessary.
3. Are there special pharmacy requirements ?					
4. Will laboratory equipment and personnel be adequate to conduct the protocol ?					
5. Will staff needs compete with other projects ?					
6. Does the sponsor require special training for the protocol ? (i.e. eCRF's of protocol procedural training)					
7. Does the sponsor provide source documents ?					If no, include additional staff time in administrative section.
8. Does the sponsor provide a consent template ?					If no, include additional staff time in administrative section.

# Comprehensive Protocol Feasibility Questionnaire

Item	Yes	No	NA	UNK	Comments
<b>VIII. Financial (Section completed by OCRSS Financial Manager)</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
1. Does the draft budget provided by the sponsor negotiable ?					
2. Does the draft budget have all expenses identified ?					
3. Is there evidence that the sponsor a solvent company ?					
4. Have we negotiated successfully with this sponsor on a budget in the past ?					
<b>IX. Study Design and Objectives</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
1. Is the protocol title clear and accurate ?					
2. Is this the final version of the protocol ?					
3. Does the protocol reflect competent preparation ?					
4. Are the objectives, rationale and activities of the study clearly stated and sensible ?					
5. Is the study justified by its scientific objectives ?					
6. Is this study similar to previous studies we have conducted, and what were the results of those studies ?					
7. What phase is the study ?					
8. Are prohibited activities required before informed consent is obtained ?					
9. Can all activities scheduled for each visit be completed in that visit ?					
10. What are the safety and efficacy endpoints for the study, and how are they measured ?					

## Comprehensive Protocol Feasibility Questionnaire

Item	Yes	No	NA	UNK	Comments
<b>X. Treatment</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
11. What is the study drug ?					
12. What is the comparator ?					
13. What is the ratio of subjects per arm ?					
14. How does study treatment differ from standard of care ?					
15. Is there a problematic washout period ?					
16. Are there technically difficult treatments, procedures or assessments ?					
<b>XI. Study Schedule</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
17. Is the schedule reasonable and practical ?					
18. When will we initiate the study and how does that date compare to other sites ?					
19. what is the enrollment period ?					
20. What is the follow-up period ?					
21. Will visits be performed outside normal business hours or create logistical challenges ?					
22. How often will the study be monitored and how will monitoring be conducted ?					
23. Are there any interim milestones, e.g., for data submission ?					

# Comprehensive Protocol Feasibility Questionnaire

Item	Yes	No	NA	UNK	Comments
<b>XI. Subject Protection</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
24. What are the benefits, risks and burdens for the subjects ?					
25. Is the use of placebo, if any acceptable ?					
26. Does the study raise any standard-of-care issues ?					
27. Is the safety profile of the study drug acceptable ?					
28. Are there any other subject protection or ethical issues ?					
29. Will the IRB have issues ?					
<b>XII. Subject Recruitment and Retention</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
30. Are the enrollment objectives - numbers and time period realistic ?					
31. Do we have access to the study population ?					
32. Where and how will we find potential subjects ?					
33. Will they be interested in participating ?					
34. Is the study duration very long ?					
35. Are the visit schedule and times acceptable for subjects and practical for study personnel ?					
36. How much flexibility is there in visit dates ?					
37. Are there frequent, inconvenient or unpleasant procedures ?					
38. Is the dosing schedule inconvenient or complex ?					
39. Are subject diaries required ?					
40. Are the eligibility criteria too strict ?					

# Comprehensive Protocol Feasibility Questionnaire

Item	Yes	No	NA	UNK	Comments
41. Are the eligibility criteria clear and unambiguous ?					
42. Are the screening procedures practical, limits and yields reasonable, and payments acceptable ?					
43. Are there seasonal issues ?					
44. Do we, or will we, have other studies competing for the same subjects ?					
45. Are other sites in the local area participating in the study ?					
46. Is enrollment competitive ?					
47. Are subjects from populations with extra recruiting and informed consent requirements ?					
48. When do subjects become evaluable ?					
49. Are subjects likely to stay in the study for its duration ?					
50. What subject recruiting support will the sponsor provide ?					
51. What costs will subjects incur ?					
52. What subject compensation make sense ?					
53. After completion of the study, how and when can subjects get access to the study drug ?					
<b>XIII. Adverse Events</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
54. How many AE's and SAE's should we expect ?					
55. What types of adverse events are recorded or reported ?					
56. What are the known side effects of the study drug ?					

## Comprehensive Protocol Feasibility Questionnaire

Item	Yes	No	NA	UNK	Comments
57. What are the implications of pre-existing medical conditions for classifying adverse events ?					
58. How is the randomization code broken ?					
59. Who pays for treating subject injuries ?					
<b>XIV. Personnel</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
60. Do we have qualified personnel available to conduct the study ?					
61. Does the study require above-normal time to conduct, e.g., visit lengths or CRF pages ?					
62. Is additional staff training required ?					
63. Are there unusual pharmacy, dispensing or accountability requirements ?					
64. Is specialist expertise required, e.g., for assessments ?					
65. Can the principal investigator delegate activities normally ?					
66. Are there any limitations on sub investigators or satellite sites ?					
<b>XV. Facilities and Equipment</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
67. Do we have access to required facilities and equipment ?					
68. Are the laboratories local or central ?					
69. Are the arrangements for shipping lab specimens practical ?					

# Comprehensive Protocol Feasibility Questionnaire

Item	Yes	No	NA	UNK	Comments
70. Are laboratory tests required when the laboratory is closed ?					
71. Do laboratory and other facilities have adequate capacity ?					
72. Do we have adequate space and equipment to store study materials and records ?					
<b>XVI. Other</b>					<input type="checkbox"/> Recommended <input type="checkbox"/> Not Recommended
73. Do we have previous experience with or references for the sponsor ?					
74. Do we have previous experience with or references for the CRO ?					
75. Do we have ready access to sponsor/CRO personnel ?					
76. Does the study budget support our financial and other objectives, such as patient care, education, physician relations, and marketing ?					
77. Is the study sponsor financially sound ?					
78. Are there third-party payer reimbursement issues ?					
79. Does the clinical trial agreement include problematic terms ?					
80. What study activities require pre-approval by the sponsor (e.g., unscheduled visits, extra lab tests, subject injury treatment, and advertising)?					
81. Will EDC/eCRF be used ?					
82. Are there unusual requirements as to how study activities are performed ?					
83. Are there unusual reporting or other administrative requirements ?					

Adapted From:

OFFICE OF CLINICAL RESEARCH SERVICES AND SUPPORT  
University of Louisville and Norman M. Goldfarb - Vol.5, No. 4, April 2009