CLINICAL TRIAL FEASIBILITY CHECKLIST FORM

Protocol Title:
Principal Investigator:
Clinical Research Coordinator(s):

Item	Yes	No	NA	UNK	Comment
I. Protocol (Section completed by PI and Clinical team)		☐ **Recommended**		☐ **Not recommended**	
1. Are there any competing trials ongoing at CW?	☐	☐	☐	☐	
• If so, will there be a sufficient number of eligible patients for this trial?	☐	☐	☐	☐	
2. Is this study similar to previous studies conducted at this site?	☐	☐	☐	☐	
• If so, were the previous studies successfully completed?	☐	☐	☐	☐	
3. Can the protocol be adequately integrated with routine standards of care?	☐	☐	☐	☐	
4. Is specialized equipment required? *If yes, comment on availability (e.g., obtain from other departments or sponsor, or must be purchased, etc.).*	☐	☐	☐	☐	
5. Is this study being conducted in patient care areas?	☐	☐	☐	☐	
5a. Are unit nurses and unit supplies required for this research protocol? If yes, a departmental sign off will be needed from the CW administrator for that area.	☐	☐	☐	☐	
5b. Are other personnel required to conduct special procedures or efficacy measures? *If yes, identify sub-specialist physicians, technicians, physical therapists, etc.).*	☐	☐	☐	☐	
5c.Will special procedures require evaluations or testing outside of regular clinic hours?	☐	☐	☐	☐	
5d.Are there specific facility requirements?	☐	☐	☐	☐	
6.. Are frequent and severe AEs expected? *If yes, comment on clinical implications and note resource effects here.*	☐	☐	☐	☐	

Item	Yes	No	NA	UNK	Comment
II. Enrollment ***(Section completed by Clinical team)***		☐ **Recommended**		☐ **Not Recommended**	
1. Are the inclusion/exclusion criteria reasonable to meet enrollment?.	☐	☐	☐	☐	
2. Will the following factors impede enrollment: *Comment on whether factors will discourage consent from parent or child.*	☐	☐	☐	☐	
• Age?	☐	☐	☐	☐	
• Duration of participation?	☐	☐	☐	☐	
• Frequency of visits?	☐	☐	☐	☐	
• Frequency of dosing?	☐	☐	☐	☐	
• Medication restrictions?	☐	☐	☐	☐	
• Other medical conditions?	☐	☐	☐	☐	
• Procedural discomfort?	☐	☐	☐	☐	
• Other medical conditions?	☐	☐	☐	☐	
• Washout period?	☐	☐	☐	☐	
3. Based on past/current knowledge, how many can be enrolled based on estimates and review?	☐	☐	☐	☐	
• 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.*	☐	☐	☐	☐	

Item	Yes	No	NA	UNK	Comment
III. Sponsor Expectations *(Section completed by PI and Clinical team)* ☐ **Recommended** ☐ **Not Recommended**					
1. Is the sponsor expected timing reasonable to enroll the number of patients expected?	☐	☐	☐	☐	
2. Can you enroll the number of subjects that the sponsor expects?	☐	☐	☐	☐	
3. Are the visit schedule and times acceptable for subjects and practical for study personnel?	☐	☐	☐	☐	

Item	Yes	No	NA	UNK	Comment
IV. Resources *(Section completed by PI and Clinical team)* ☐ **Recommended** ☐ **Not Recommended**					
1. Will extended staff hours be required? *Comment on after-hour or weekend requirements for 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. Does the sponsor require special training for the protocol? (i.e. eCRF or protocol procedural training)	☐	☐	☐	☐	
6. Does the sponsor provide source documents? *If no, include additional staff time in administrative section.*	☐	☐	☐	☐	
7. Does the sponsor provide a model consent template? *If no, include additional staff time in administrative section.*	☐	☐	☐	☐	
8. Is the imaging standard of care? *This will be evaluated and may not be considered standard of care in its entirety after review of imaging protocol-* ***for help with the process of getting CW Imaging Approval as well as addressing any questions related to imaging needs, please contact: CWHRPP@childrenswi.org***	☐	☐	☐	☐	
8a. Are you using imaging in your study-***if CW imaging services are being used for research, you will need you will need to complete the imaging intake form. You will need imaging approval and likely CW raditiaon safety and WI state DHSS radiation approval. If any imaging is being done with FH or MCW resources, MCW safety committee approval may also be required.***	☐	☐	☐	☐	
MR	☐	☐	☐	☐	
CT	☐	☐	☐	☐	
PET	☐	☐	☐	☐	
PET/CT	☐	☐	☐	☐	
8b. Do you require image analysis, data transfer (If yes additional resources are required)	☐	☐	☐	☐	.
9. Does the sponsor require equipment and site qualification *If yes additional resources are required.*	☐	☐	☐	☐	

Item	Yes	No	NA	UNK	Comment
V. Sponsor/CRO *(Section completed by PI and Clinical team)* ☐ **Recommended** ☐ **Not Recommended**					
1. Is this a PI-initiated study?					
• If so, is there a commitment from a sponsor to fund this trial?	☐	☐	☐	☐	
3. What is duration of project?					
4. Are there other considerations, which would increase complexity of study conduct? (e.g - does this project involve needing an IND or IDE from the FDA) If yes please describe additional resources required	☐	☐	☐	☐	

PI Signature:	Date	Overall Assessment
		☐ Feasible
		☐ Not Feasible

Save Form