UCSF CLINICAL TRIAL FEASIBILITY CHECKLIST FORM

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 REQIREMENTS.

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

Protocol Title:

Potential Principal Investigator:

Clinical Research Coordinator(s):

I. Protocol ***(Section completed by PI and Clinical team)***	**Yes**	**No**	**N/A**	**Unk**	**RECOMMENDED ☐** **NOT RECOMMENDED ☐**
1. Are there any competing trials ongoing at UCSF?					
• 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 (should it be *your or this)* site?					
• If so, were the previous studies successfully completed? (should we add including recruitment?) (not needed cause if successful, recruitment must have been ok.					
3. Can the protocol be adequately integrated with routine standards of care?					
4. Is specialized equipment required?					
5. Is this study being conducted in patient care areas?					
• If yes, has the PI met and discussed the proposed project with nursing leadership of the involved units and obtained a support letter(s) to be included with the CHR protocol submission?.(are we requiring a letter of support and/or providing a template?) we should ask Daphne for a template					
6a. Are unit nurses and unit supplies required for this research protocol? If yes, specify (should be addressed in Primary Care Managers (PCM) support letter(s).					
6b. Indicate if using Clinical Research Services (CRS) nursing services.					
7. Are other personnel required to conduct special procedures or efficacy measures?					
• Will special procedures require evaluations or testing outside of regular clinic hours?					
8. Are frequent and severe AEs expected?					
9. In which facility should this study be done?					
10. Could subject compliance be an issue?					
11. Will drug be available at the end of the study for continued treatment of the patient?					

II. Enrollment *(Section completed by Clinical team)*	**Yes**	**No**	**N/A**	**Unk**	**RECOMMENDED ☐**	**NOT RECOMMENDED ☐**
1. Are the inclusion/exclusion criteria reasonable to meet enrollment?. (I don't understand this-are you asking for actual exclusion criteria?)						
2. Will these factors impede enrollment:						
• 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?						
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?						

III. Sponsor Expectations *(Section completed by PI and Clinical team)*	**Yes**	**No**	**N/A**	**Unk**	**RECOMMENDED ☐**	**NOT RECOMMENDED ☐**
1. Is the sponsor expected timing reasonable to enroll the number of patients expected?						
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?						

IV. Sponsor / CRO *(Section completed by PI and Clinical team)*	**Yes**	**No**	**N/A**	**Unk**	**RECOMMENDED ☐**	**NOT RECOMMENDED ☐**
1. Is this a PI-initiated study?						
• If so, is there a commitment from a sponsor to fund this trial?						
2. Do you have previous experience with the CRO/sponsor?						
3. What is duration of project?						
4. Are there other considerations, which would increase complexity of paperwork?						

V. Resources *(Section completed by PI and Clinical team)*	**Yes**	**No**	**N/A**	**Unk**	**RECOMMENDED ☐** **NOT RECOMMENDED ☐**
1. Will extended staff hours be required?					
2. Is current staffing adequate to conduct the trial?					
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?					
7. Does the sponsor provide a consent template?					
8. Is the imaging standard of care					
9. Does the sponsor need equipment and site qualification					
10a. Are you using imaging in your study ?					
MR					
CT					
PET					
PET/CT					
10b. Have you received an Imaging Approval Number prior to contract negotiation? If yes please provide it.					
11. Do you require image analysis, data transfer					

PI Signature

Date

OVERALL ASSESSMENT:

FEASIBLE **NOT FEASIBLE**