Icahn School of Medicine at Mount Sinai

Conduits
The Institutes for Translational Sciences

Protocol Feasibility Checklist

Protocol Number:	**Protocol Title:**
Phone Number:	**Email:**
Does your practice have access to the patient population? **Yes** □ **No** □	
Recruitment strategies: (**circle all that apply**) in-house databases, chart reviews, paid advertising, pre-screening, physician referrals, affiliate hospitals, other	
Please explain your recruitment plan(s), including external sources	
Should sponsor provide recruitment funding? **Yes** □ **No** □	
Will sponsor provide marketing materials? **Yes** □ **No** □	
What is your proposed enrollment goal?	
What is the proposed enrollment period?	
Will enrollment compete with other studies seeking the same population? If yes, please explain which studies and how you plan to prioritize **Yes** □ **No** □	
Will any of the inclusion/exclusion criteria lead to large number of screen failures? If yes, please explain **Yes** □ **No** □	

Protocol (to be completed by PI)

Will coordination with other departments/services be required for study visits or procedures? If yes, please explain **Yes** □ **No** □
Is the study unusually long in duration? If yes, please explain **Yes** □ **No** □
Are patient compliance problems likely and/or early termination/drop out likely? **Yes** □ **No** □
If yes, will it be necessary to monitor subjects' compliance with follow up? **Yes** □ **No** □
Are drug or device being provided by the sponsor, If no, please explain **Yes** □ **No** □
Does the sponsor hold the IND? If no, please explain **Yes** □ **No** □

Is the protocol in final form? If not, when will it be expected before it is in final form? **Yes** □ **No** □
How will the subjects benefit from participating in the study?
Is the protocol ethical or will the IRB have problems with it? **Yes** □ **No** □
Is the sponsor willing to consider suggestions or modifications if you do not think the protocol is feasible as written? **Yes** □ **No** □
Do you expect a significant number of adverse events? If yes, please explain **Yes** □ **No** □
Are any of the procedures too frequent, difficult, or painful than the standard of care for this patient population? **Yes** □ **No** □
Is the dosing schedule complex? **Yes** □ **No** □
How is study drug administered?

Staff (To be completed by CCTO Administration)

What is the required staffing level? ❑ RN ❑ CRC ❑ BOTH
Is this an in-patient or out-patient study? ❑ FPA, ❑ FLOOR, ❑ Clinical Research Unit ❑ Other, explain
Will additional staff need to be involved and/or trained? **Yes** □ **No** □
Are case report forms complex or are there a large number of case report forms per subject? **Yes** □ **No** □
Will the study require a dedicated data coordinator? **Yes** □ **No** □
Will electronic or remote data retrieval systems be used? If so, will sponsor provide training? **Yes** □ **No** □
Is a draft consent form provided by the sponsor? **Yes** □ **No** □
Is the workload manageable? **Yes** □ **No** □
Does the PI have adequate time to devote to the protocol? **Yes** □ **No** □
Are additional specialists needed? **Yes** □ **No** □
Are study visits complex, presenting possible scheduling difficulties? **Yes** □ **No** □

How many different study staff members will subjects encounter in a given visit?		
Is necessary equipment available?	**Yes** □	**No** □
Will research pharmacy storage/accountability be required?	**Yes** □	**No** □
Is projected query turnaround time workable?	**Yes** □	**No** □
Is adequate clinic and office space available?	**Yes** □	**No** □
Does the sponsor expect this study to be audited by the FDA?	**Yes** □	**No** □
What is the frequency of monitor visits?		
Will the monitor need to meet with the PI at every visit?	**Yes** □	**No** □

Budgets (to be completed by Finance)

Does sponsor's preliminary budget appear adequate? If not, what are the challenges?	**Yes** □	**No** □
Has your previous experience with this sponsor/CRO been satisfactory?	**Yes** □	**No** □
If you've had no previous experience with this sponsor/CRO do you need to investigate their reputation?	**Yes** □	**No** □
Will the proposed payment schedule allow you to keep afloat, e.g., adequate up-front payment; payments paced according to work required by protocol?	**Yes** □	**No** □
Is this a Qualifying Clinical Trial?	**Yes** □	**No** □
Will this trial require a Medicare Coverage Analysis?	**Yes** □	**No** □

Other

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