PANDORA: Scheduled Prophylactic 6-Hourly IV AcetaminopheN to Prevent Postoperative Delirium in Older CaRdiac SurgicAl Patients: A Randomized Controlled Trial

Feasibility Questionnaire

PI Name:	_____	Contact person	
Institution:	_____	for this submission:	
Area of practice:	_____	_____	
Date:	_____	_____	

Patient population

This study targets adult patients aged 60 years or older undergoing CABG or combined CABG/valve (aortic and/or mitral) cardiac surgery procedures. Estimate to the best of your ability the **number of patients you could enroll** per month. _____

This study allows co-enrollment with observational studies, but will prohibit co-enrollment with interventional trials. Please describe any **competing trials** currently running at your site and your proposed approach to resolving conflicts. _____

_____

Clinical Practice

What percentage of your cardiac surgical population have **liver function tests** (AST and ALT) ordered clinically in the 30 days prior to surgery? _____

Please describe your local approach to **intraoperative sedation** for eligible cases: in a recent 12-month block, what percentage of patients aged 60 years or older undergoing CABG or combined CABG/valve (aortic and/or mitral) cardiac surgery procedures received:

_____ % propofol
_____ % dexmedetomidine
_____ % both
_____ % neither / other (please specify: _____)

Please describe your local practice of **patient mobilization** after cardiac surgery? Do you have a mobilization protocol at your institution (if yes, please attach):

_____

Please describe your local adherence to **Enhanced Recovery after Surgery** (ERAS) or other guidelines and pathways:

_____

Does your site participate in the Society of Thoracic Surgeons (STS) National Database - STS Adult Cardiac Surgery Database (ACSD)? ❑ Yes / ❑ N

Does your site collect Intraoperative Hypotension (IOH) Data? ❑ Yes / ❑ N

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Clinician collaboration

This is a long-running study. Do you anticipate being able to add several other physician colleagues as **co-investigators**? This arrangement can provide better coverage and flexibility for your research staff if they find eligible patients or have questions on active patients while you are unavailable. Please describe your approach:

_____

The intervention consists of administration of 8 doses of study drug q6h. Involvement and support of nursing staff is essential. Please describe your experience engaging **CVICU nursing** staff in drug studies: _____

Research team

Please describe your team, including their availability and their experience with clinical research.

- Who will identify eligible patients?
- Who will obtain informed consent?
- Who will conduct neurocognitive assessments?
- Who will monitor for drug regimen compliance?
- Who will collect the specimens?
    - Will a separate venipuncture charge be required to collect research blood samples? _____
- Who will collect the data?

Please describe your staffing model – will you be able to cover enrolled patients on evenings and weekends such that medication administration is monitored, and assessments and blood draws are performed per protocol? _____

Research Pharmacy

Please indicate the **minimum time** your research pharmacy requires between randomizing a patient and having the first drug of study drug prepared for administration: _____

Is your research pharmacy familiar with **creating matching placebo**? Would your pharmacy staff be able to undertake this with a standardize pharmacy operations manual and guidance from the clinical coordinating center?

_____

Do you or your research pharmacy have any concerns? _____

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Investigator experience and obligations

How many clinical trials have you conducted in the **past five years**? _____

How many **active studies** are you enrolling for currently? _____

Laboratory

This study involves collecting blood at three time points. Minimal local processing (centrifugation and micropipetting of specimen into aliquots) is necessary. **Please describe your research laboratory set up.** E.g., Can your research team do the blood processing? Can dedicated lab personnel do the processing? Do you have access to a centrifuge and freezer overnight and on the weekends? Do you utilize a CTSA or other central laboratory?

_____

Regulatory

Please describe **the local review process** when IRB oversight is ceded to another institution (e.g. how long does initial approval to cede review take; is subsequent local review of amendments required):

_____

Costs

Please indicate the local cost for:

- Alanine Aminotransferase (ALT) [CPT 84460] _____
- Aspartate Aminotransferase (AST) [CPT 84450] _____
- Ibuprofen, 1 gram, IV formulation _____
- Placebo manufacture _____
- Research Pharmacy start-up costs _____
- Indirect cost rate (NIH) _____
- R&A percentage _____

Any other considerations or concerns

Please feel free to add any other information that might be useful at this stage.