APPLICATION FOR CENTRAL AGMC PEER REVIEW

A voluntary central peer review process has been developed at AGMC to ensure that *investigator-initiated* protocols submitted for review to the IRRB and IACUC have undergone an independent and rigorous review to assess scientific quality. Use of this centralized peer review resource to perform a review of protocols written by AGMC investigators prior to their submission is optional and should be utilized by departments or individuals that do not already have access to a peer review resource as specified in the Akron General Medical Center Peer Review Policy. Protocols will be reviewed for content, methodology, and basic statistics. The Basic Science and Clinical Science Reviewers will work to ensure a rapid turn around time, however the peer review process should be considered one step in the study development process and not a solution to developing a sound study within a few days in order to meet an IRRB or funding deadline. A thorough research proposal should be submitted together with this completed form to Department of Research c/o Diane Post at Diane.Post@akrongeneral.org.

Title of Protocol_____

PI_____

Other Investigators_____

Person requesting review_____

Date review requested _____

(Note: After the AGMC Peer Review is completed, please attach comments received, as well as your response to the comments, with the protocol submission to IRRB or IACUC. If you have received a review from another source (for example, NEOMED), please attach those comments, and your response as well, to the protocol submission to IRRB or IACUC.)

Akron General Medical Center
Peer Review Checklist- Investigator Initiated Research

PART A (Completed by Principal Investigator/PI)

Title of Protocol**:**.	
Type of Protocol: (examples: treatment, prevention, quality of life, Phase 1) describe:	
Sponsor (Funding source; if applicable):	
Principal Investigator(s):	
Other Investigator(s**):**	
Study Coordinator(s)/Data Management**:**	
Indicate the target number of subjects to be enrolled at the site.	
Have all involved departments/services reviewed the protocol for feasibility and provided feedback?	
Does this protocol compete with other protocols in the AGHS system? (CHECK AGMC INTERNET)	
Have all the Investigators/sub-investigators met Human Subjects Research Investigator Training and Credentialing Requirements?	
Attach COI disclosure forms for all Investigators DOES A POTENTIAL COI EXIST? _____Yes _____NO (If Yes, refer to COI Policy)	Cognizant Official: print name, initial and date

PART B (Signatures)

If submitted to outside funding agency Grant Accountant must review and approve budget	Grant Accountant: print name, initial, and date:
CLINICAL REVIEW: The review of clinical relevance should include, but not be limited, to the following - The methods/practices of the protocol are acceptable to the discipline. - The clinical objectives and endpoints of the protocol are clearly defined. - The number of subjects available is adequate to meet accrual goals of the protocol. - The use of any non-standard of care exams/procedures/labs that should be charged to the study and not to the patient or the patient's insurance are clearly defined by the investigator.	Qualified clinical reviewer: print name, initial, affiliation and date.
STATISTICS/METHODOLOGY REVIEW : Scientific review, including study design, methodology, sample size/power analysis, statistical analysis, has been conducted.	Qualified statistical reviewer: print name, initial, affiliation and date:
Please attach comments concerning this submission and associated peer review.	

I certify that this protocol has undergone the peer review process:

_____ _____
Department Peer Review Administrator (print name and initial) Date

_____ _____
Cognizant Official (print name and initial) Date

When this form is complete, please sign and return to:_____

RES-001.5
Approved by Medical Council 7/13/10