Requirements for Approval of Continuing Review
Jackson State University Institutional Review Board

Name:

Address:

City, State, Zip:

Phone: (daytime):

Phone: (evening)

Fax:

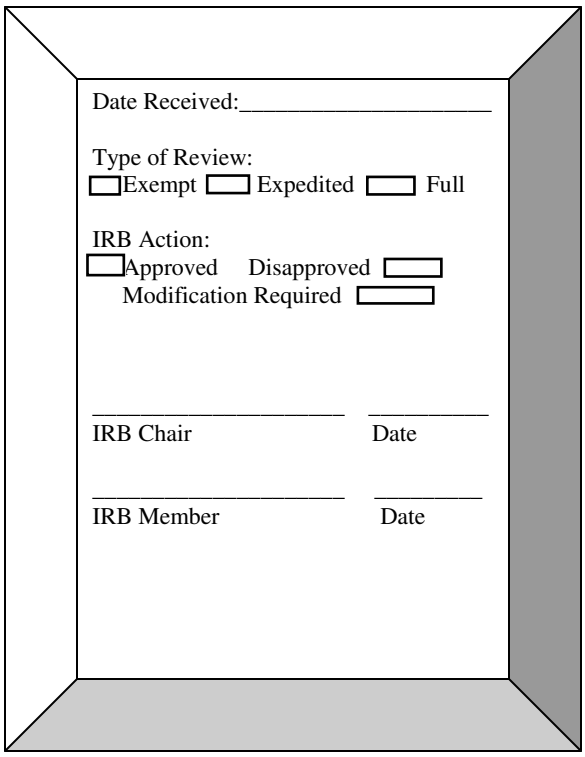
E-mail:

Department/Unit:

Title of Project:

Research Project Period:

Sites of Research:



Please include the following elements in request for extension of a protocol. If the element does not apply to your study, then respond N/A:

a) ___ Number of subjects enrolled

b) ___ Number of subjects screened

c) ___ Number of subjects withdrawn

d) ___ Reasons for withdrawal

e) ___ Number of subjects dropped out of protocol

f) ___ Reasons for dropout

g) ___ Number of subjects lost to follow-up

h) ___ Gender and ethnic/racial breakdown of enrolled subjects

i) ___ Verification that informed consent was obtained from all subjects and that

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all signed consent forms are on file (unless requirements were waived)

j) ___ Number of serious adverse events (SAEs)

k) ___ Description of SAEs

l) ___ Number of unanticipated problems

m) ___A description of the unanticipated problems

n) ___ List of amendments or modifications since last IRB review

o) ___ Change in study personnel

p) ___ Change in sponsor

q) ___ Subject complaints

r) ___ Summary of progress/preliminary findings

s) ___ Other: _____

Please Include the Items Marked (if applicable)

Items Collected for Continuing Review		Distributed for Full Committee Review			
Item	Requested by IRB	Chair	Primary Reviewer	Other IRB Members	Alternate Members
a) IRB's written status report form [See above list]	X				
b) Copy of informed consent form(s) used during the past approval period	X				
c) Protocol summary	X				
d) Protocol/project modifications	X				
e) Summary of recent literature	X				
f) NIH Progress Report	X				
g) DSMB Progress Report	X				
h) Application					

_____ _____

Applicant's Name **Date**

_____

Signature