

Protocol Amendment Form

<u>RADS-IRB REF. Number</u> (RADS-IRB will not process requests without this number.)	<u>Date of Request</u>
Principal Investigator Name: Phone #: <u>Email:</u>	Contact Person (if other than PI): <u>Phone #:</u> <u>Email:</u>
Title of Study	

Instructions to Principal Investigator: No amendment can be implemented before approval by RADS-IRB except for those relating to participants safety. Participants safety related amendments should be submitted as soon as possible. Please ensure that all sections of this form are completed. For all blank sections indicate N/A as appropriate:
(PI to tick appropriate box and ensure that appropriate fee is paid)

EXPEDITED REVIEW <i>(Applicant may expect response within 10 working days of submission of complete application and required documents)</i> Expedited Review charges (PKR 90,000 + GST) Medium Amendment charges (35% of Expedited Review charges + GST)		STANDARD REVIEW (full committee review) <i>(IRB panel convenes on the last week of every other month; starting from January 2021. (Please submit your application 15 working days prior to IRB convening date)</i> Standard Review charges (PKR 60,000 + GST) Medium Amendment charges (35% of Expedited Review charges + GST)	
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Date accepted by RADS-IRB (to be completed by RADS-IRB Secretary)	
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ONLY FOR RADS-IRB OFFICE USE:

£	Qualifies for expedited review	£	Qualifies for full committee review
Other Comments:			
IRB Administrator's Signature:			Date:

PROTOCOL AMENDMENT REQUEST SUBMISSION CHECKLIST

Applicant to complete all sections and provide supporting documentation for all checked items.

	Applicant	IRB-Committee
Amendment form fully completed and signed		
Has the PI provided justification for the amendment request?		
Has the PI provided a new/revised proposal with track changes		
Are new/revised consent forms required?		
Are new/revised interview/instruments/questionnaires/recruitment materials required?		
Are translated consent forms required?		
Previous approval letters attached		
Evidence of payment of research review fees		
Soft copy been submitted		
Other supporting documentation (specify)_____		

1. Detailed description of proposed changes: (Note: Changes may not be implemented before RADS-IRB approval)

2. Reason for Amendment/Modification:

3. Are changes required to the consent form? No _____ Yes _____ (If Yes, attach new consent form)

_____ Signature of Principal Investigator	_____ Date
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RADS-IRB Office Use only:

Approval of Changes /Modifications by RADS-IRB

Recommended: _____

Not recommended: _____

Approved by: _____

Approval date: _____

Signature: _____
(IRB Chairperson or Authorized Signatory)

Date: _____