University Malaya Medical Centre

IResearch System

User Manual

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1.0 User Manual For Applicant

1.1 New Application

- 1) Login to Portal <u>my.ummc.edu.my</u>
- 2) Click on eservices-> iResearch

MALAYA USAT PERUBATAN UM		34	WUM	MC	
NGGUNA : NOR 'ALIA BINTI RA	MLAN			Kata Ki	unci :
Notifikasi	Umum Pen	tadbiran K	linikal Sokongan Klinik	al Manual Penggun	a Muat Turun
Latihan/kursus (3)			Umum.		
tama	1.1		C		
erroral	4		Emel PPUM		Posed Percenter
Servis	Maklumat Kakitangan	Aduan Pelar	nggan Emel	Permohonan SSC) ez Form
anduan relefon	· · · · · · · · · · · · · · · · · · ·				
skeliling	K 🚬	5.6	7-1	0000	Baltuman
emakan	HELPDESK NADUUT	X		SEI	Routin
enyeliaan	Aduan ICT	Web Wo	rk Pengurusan Stor	Portal OSH	Dokumen Kualit
entadbir Sistem					
autan	Borner	RISK			Madaa
og Keluar	Lauden			N.COMO	Roberten
	burany Insiden	e-RISIKO	rempanan Fasiin	MYEDMS	T Kesearch

3) iResearch Dashboard



4) Instruction to apply.

INSTRUCTION TO APPLY*

- Only Principal Investigator from UMMC/Faculty of Medicine are allowed to apply through this portal (who has Single Sign On (SSO) Username and Password).
- 2) Please submit your application at least one (1) week before the Deadline of Acceptance by Secretariat (Refer table at No.8).
- 3) Please complete every stage of application before you save and proceed.
- 4) DO NOT LEAVE the text field in blank. Please put NONE for any field which are not applicable to your study project. 5) Please prepared the following documents (if applicable) to be uploaded along the stage of application:
 - i) Resume and GCP certificate
 - ii) Study protocol iii) Patient Information Sheet in English and translated languages
 - iv) Consent form in English and translated languages v) Insurance certificates vi) Investigator's Brochure

 - v) Any other documents which support the study project.
- 6) For any Interventional Clinical Research which involves drugs, please register into the National Medical Research Register (NMRR) https://www.nmrr.gov.my.
- 7) Principal Investigator will be contacted through phone call and email if the study needs to be presented in monthly MEC meeting.
- 8) MEDICAL ETHICS COMMITTEE DEADLINE SUBMISSION AND MEETING SCHEDULE FOR YEAR 2015

DEADLINE ACCEPTANCE BY SECRETARIAT*	DATE OF MEETING*	VENUE*
9 JAN	21 JAN	PUSPASARI
6 FEB	25 FEB	LILI
6 MAR	25 MAR	PUSPASARI
10 APR	22 APR	PUSPASARI
8 MAY	20 MAY	PUSPASARI
5 JUNE	17 JUNE	PUSPASARI
10 JUL	29 JUL	PUSPASARI
7 AUG	19 AUG	PUSPASARI
4 SEPT	30 SEPT	PUSPASARI
9 OCT	21 OCT	PUSPASARI
6 NOV	25 NOV	PUSPASARI

Please call Secretariat (En.Mohd Izanie Che Yusoff) at 603-79492251/3209 if you need any assistance

CONTINUE >>

5) Application Form

•	Instruction To Apply Mair	Menu Application Status	
ew Application Form			
TEP1 : GENERAL INFORMATION	STEP2 : RESEARCH DETAILS	STEP3 : PROJECT INFORMATION	STEP4 : METHODOLOGY
STEP5 : ETHICAL ISSUES STEP	5 : REVIEW & SUBMIT		
General Information			
1. Project Title*			
· · · · ·			
2. Protocol.No			
3. Research Type*	- Select -	T	
4. Clinical Research Sub-Type*	- Select -	τ	
5. General Area*	- Select -	•	
6. Therapeutic Area*	- Select -		
	- Select -		
/. Disease Area			
Cancer	Haematology disorder	Cardiovascular disorder	Metabolic /
Cancer including	Anemia		Endocrine disorder
Leukaemia		Cerebrovascular disorder /	Hyperlipidarmias
		Stroke	Obesity Metabolic Syndrome
		Heart Failure	_ nearbone syndrome

1)STEP1: General Information 2)STEP2: Research Details 3)STEP3: Project Information 4)STEP4: Methodology 5)STEP5:Ethical Issues 6)STEP6: Review & Submit - Check all information and submit application.

6) Application status

| Main Menu |

	Application Information											
1	۱o.	MECID.No	NMRR.ID	Project Title	Applicant	Date of application	HOD Comment	CIC Verification	SMEC Verification	CMEC/DCMEC Approval	Status	
	1	20141-1	NM902	Test Research 2014	NOR 'ALIA BINTI RAMLAN	2/25/2014 4:24:16 PM		×	>	×	Keputusan- Terima	view

-Notification (Application have been approved and applicant should register study with NMRR (<u>www.nmrr.gov.my</u>). Then update application with NMRR ID number.



view - View application form



- Print approval letter

1.2 Update NMRR ID Number



1.3 Notification : Returned Application



I	New A	oplication Form		
(Ple	ase update your resume.To	1	Returned
ſ	STEP1	: GENERAL INFORMATION	STEP2 : RESEARCH DETAILS STEP3 : PROJECT INFORMATION	application reason.
	STEP4	: METHODOLOGY STEP5	: ETHICAL ISSUES STEP6 : REVIEW & SUBMIT	
	Gen	eral Information		
	1.	Project Title*	Clinical Trial Agreement	
	2.	Protocol.No	123456	
	з.	Research Type*	Clinical	
	4.	Clinical Research Sub-	Interventional Study : Clinical Trial/Clinical Research	

2.0 User Manual for Head of Department

C	N	atifikaci					Senarai	Permoho	onan Peny	elidikan \	/ang Pe	erlu Dis	sahkan			
	Curti (2)	UIIKasi		Kelulusa	n Ketu	ia Jabatan Per	nyelidikan (1	· <								
	Edms (31)															
	Latihan/ku	rsus (6)														
→	Penyelidika	n (Ethics)	(1)													
U	Jtama															
				NE		SEARCH AE	ΡΕΙ ΤΟ ΔΤΤΟ)N								
No.	MECID.No	Project Title	Applican	nt Date applic	of ation	Approval SMEC	Approval HOD	Approval CIC	Approval Director	Approval CMEC	Status			٢		
1	20143-2	Test research 2014	NOR 'ALIA BINTI RAML	AN 3/3/20: 3:31:17	L4 PM						Akuan Ketua	view	<	-L	5	
				PREVI	ous	RESEARCH	APPLICA	ΓΙΟΝ								
No.	MECID.No	Project Title	Applicant	Date of application	A	Approval SMEC	Approval HOD	Approval CIC	Approv	al App or Cl	roval MEC	Status				
		_		HEAD OF	DEPA	ARTMENT RE	COMMEND	ATION					/			
														L	4	
Con	nment	:														
								1								
					S		SET									

3.0 User Manual for other department involve(HOD).

Notif	fikasi	Senarai Permohonan Penyelidikan Yang Perlu Disahkan
Cuti (3)		Sokongan Ketua Jabatan (Permohonan Fasiliti)(1)
Edms (31)		
Latihan/kursu	IS (6)	
→ Penyelidikan (Ethics) (1)	
		HEAD OF DEPARTMENT APPROVAL (FACILITIES)
Status	: Appro	ve T
Comment		
Comment	:	
Comment	:	

3

4.0 User Manual for CIC

4.1 New application verification

Login to (http://icic.ummc.edu.my/login.asp)

UNIVIO OF M CLINICAL INVESTIG	ERSIT ALAY Ation cent	Y Clinic	al Inves	ligalio	m Centr Inform	C nation Syst	em	i-	CIC		
			Userna Passwo	Systen me : ord :	n Login]					
			Be	est wiew with	Internet Explore	er 6 or above.					
Notificat	ion : Menu Resea Trial F	irch Applica Profile	tion (1) <	<	1)					
	Resea	rch Applica	tion								
-											
ĺ	Rese	arch Applica	tion(1)	NMRR.ID	Validation						
	No.	MECID.No	NMRR.ID	Project Title	Applicant	Date of application	HOD Comment	CIC Verification	SMEC Verification	CMEC/DCMEC Approval	Status
	1	20143-2		Test research 2014	NOR 'ALIA BINTI RAMLAN	03/03/2014 15:31:17	 Image: A start of the start of				Akuan Ketua(Alatan)- Terima
						PREVIOUS	RESEARCH		N		
						1 1003	- ALDEARCI	- ALLERING			

PREVIOUS RESEARCH APPLICATION								
No. MECID.No NMRR.ID T	oject ïtle Applicant	Date of application	HOD Comment	CIC Verification	SMEC Verification	CMEC/DCMEC Approval	Status	

			CIC VERIFICATION	
Status	:	Verified Verified Not Verified		4
Comment	:	Need Director's Comment		
			SUBMIT RESET	

view

3

4.2 NMRR ID validation

ew Re	search Application					1.NMRR.ID
New F	Research Application NMRR	T				
No	Name	Title	NMRR.ID	Action		
1	Adlinda Alip	New medical research	3456	Valid 🔍 Not Valid 🔍		
2	NOR 'ALIA BINTI RAMLAN	Medical research 05032014	NM901	Valid 🔍 Not Valid 🔍		
3	NOR 'ALIA BINTI RAMLAN	Research Test 23012014	NM444	Valid 🔍 Not Valid 🔍 🗲		2.Select action
4	NOR 'ALIA BINTI RAMLAN	Research 24012014	1234	Valid 🔍 Not Valid 🔍		
5	NOR 'ALIA BINTI RAMLAN	asdasd	NM333	Valid 🔍 Not Valid 🔍		
6	NOR 'ALIA BINTI RAMLAN	Research 06022014		Valid 🔍 Not Valid 🔍		
7	NOR 'ALIA BINTI RAMLAN	Medical research	NM344	Valid 🔍 Not Valid 🔍		
8	Adlinda Alip	Medical Students as Mediators of Change in Tobacco Use	NM3456	Valid 🔍 Not Valid 🔍		
9	Adlinda Alip	ert	56	Valid 🔍 Not Valid 🔍		
10	NOR 'ALIA BINTI RAMLAN	Test Research febuari2014	45667	Valid 🔍 Not Valid 🔍		
				Submit Cancel	╡──	3.Submit

4.3 Clinical Trial Aggreement(CTA) validation

New R	esearch Application				1.Download CTA
New	Research Application NMI	RR.ID Validation CTA Verification Budget Verification			
No	Name	Title	CTA File	Action	
1	Adlinda Alip	New medical research		Approve 🔍 Not Approve 🔍	
2	NOR 'ALIA BINTI RAMLAN	Research Test 23012014	\bigcirc	Approve O Not Approve O	2.Select action
3	NOR 'ALIA BINTI RAMLAN	Research 24012014	\bigcirc	Approve 🔍 Not Approve 🔍	
4	NOR 'ALIA BINTI RAMLAN	asdasd		Approve 🔍 Not Approve 🔍	
5	NOR 'ALIA BINTI RAMLAN	Research 06022014		Approve 🔍 Not Approve 🔍	
6	NOR 'ALIA BINTI RAMLAN	Medical research		Approve 🔍 Not Approve 🔍	
7	Adlinda Alip	Medical Students as Mediators of Change in Tobacco Use		Approve 🔍 Not Approve 🔍	
8	Adlinda Alip	ert		Approve 🔍 Not Approve 🔍	
9	NOR 'ALIA BINTI RAMLAN	Test Research febuari2014		Approve 🔍 Not Approve 🔍	
10	NOR 'ALIA BINTI RAMLAN	Medical research 05032014		Approve 🔍 Not Approve 🔘	
				Submit Cancel	3.Submit

4.4 Budget validation

Net	N Re	esearch Application		1.Download f			
	ew i	Research Application NM	IRR.ID Validation CTA Verification Budget Verificat	ion		1	
[No	Name	Title	Budget File	Action		
	1	Adlinda Alip	New medical research		Approve 🔍 Not Approve 🔍	(
	2	NOR 'ALIA BINTI RAMLAN	Research Test 23012014		Approve 🔍 Not Approve 🔍	_	2.Select action
	3	NOR 'ALIA BINTI RAMLAN	Research 24012014		Approve O Not Approve O	l	
	4	NOR 'ALIA BINTI RAMLAN	asdasd		Approve O Not Approve O		
	5	NOR 'ALIA BINTI RAMLAN	Research 06022014		Approve O Not Approve O		
	6	NOR 'ALIA BINTI RAMLAN	Medical research		Approve 🔍 Not Approve 🔍		
	7	Adlinda Alip	Medical Students as Mediators of Change in Tobacco Use		Approve 🔍 Not Approve 🔍		
	8	Adlinda Alip	ert		Approve 🔍 Not Approve 🔍		
	9	NOR 'ALIA BINTI RAMLAN	Test Research febuari2014		Approve O Not Approve O	(
	10	NOR 'ALIA BINTI RAMLAN	Medical research 05032014		Approve 🔍 Not Approve 🔍		3.Submit
					Submit Cancel	_(

5.0 User Manual for SMEC (Medical Ethics Committee Secretariat)



Semakan Medical Ethics Sekretariat(1)

Senarai Permohonan Penyelidikan Yang Perlu Disahkan

	NEW RESEARCH APPLICATION										
No.	MECID.No	Project Title	Applicant	Date of application	Approval SMEC	Approval HOD	Approval CIC	Approval Director	Approval CMEC	Status	
1	20143-2	Test research 2014	NOR 'ALIA BINTI RAMLAN	3/3/2014 3:31:17 PM		\checkmark	\checkmark			Penerimaan CIC-Terima	view

	PREVIOUS RESEARCH APPLICATION									
N	o. MECID.No	Project Title	Applicant	Date of application	Approval SMEC	Approval HOD	Approval CIC	Approval Director	Approval CMEC	Status

		SECRETARIAT ACCEPTANCE	
Status	:	Accept Accept Return to applicant	4
Comment	:		
		SUBMIT RESET	

6.0 User Manual CMEC (Medical Ethics Committee Chairperson)

	Notifika	si		Sena	rai Permol	honan Pen	yelidikan `	ang Perlu	Disahkan		
Penyelidikan (Ethics) (1)											
				NEW R	RESEARCH	APPLICA	TION				
No.	MECID.No	Project Title	Applicant	Date of application	Approval SMEC	Approval HOD	Approval CIC	Approval Director	Approva CMEC	Status	
1	20143-2	Test research 2014	NOR 'ALIA BINTI RAMLAN	3/3/2014 3:31:17 PM	 Image: A start of the start of	\checkmark	V			Semakan SMEC- Terima	view
]						1		
				PREVIOU	S RESEAR	CH APPLI	CATION		1		
No.	MECID.No	Project Title	Applicant	PREVIOU Date of application	S RESEAR Approval SMEC	CH APPLI Approv HOD	CATION /al Appro	val App Dire	proval ector	Approval CMEC	Status
No.	MECID.No	Project Title	Applicant	PREVIOU Date of application	S RESEAR Approval SMEC	CH APPLI Approv HOD	CATION al Appro CIO	val App Dire	proval ector	Approval CMEC	Status
No.	MECID.No	Project Title	Applicant	PREVIOU Date of application	S RESEAR Approval SMEC AIRMAN/D	CH APPLI Approv HOD	CATION /al Appro CIO	PPROVAL	oroval ector	Approval CMEC	Status
No.	MECID.No	Project Title	Applicant MEDIC	PREVIOU Date of application CAL ETHICS CH	S RESEAR Approval SMEC AIRMAN/D	CH APPLI Approv HOD EPUTY CH/	CATION /al Appro CIC	val App Dir PPROVAL	ector	Approval CMEC	Status
No.	MECID.No	Project Title	Applicant MEDIC	PREVIOU Date of application CAL ETHICS CH	S RESEAR Approval SMEC AIRMAN/D	CH APPLI Approv HOD EPUTY CH/	AIRMAN A	PPROVAL	ector	Approval CMEC	Status
No.	MECID.No	Project Title	Applicant MEDIC.	PREVIOU Date of application	S RESEAR Approval SMEC AIRMAN/D	CH APPLI Approv HOD	AIRMAN A	PPROVAL	ector	Approval CMEC	Status
No. Statu	MECID.No	Project Title	Applicant MEDIC e e or Meeting d to Secretaria	PREVIOU Date of application CAL ETHICS CH/	S RESEAR Approval SMEC AIRMAN/D	CH APPLI	AIRMAN A	PPROVAL	ector	Approval CMEC	Status

SUBMIT RESET

7.0 User Manual for Table for Meeting

	Notifika	si		Sena	rai Permol	nonan Pen	yelidikan \	ang Perlu	Disahkan		
► Per	iyelidikan (Ethi	cs) (1)	Table for Meeting		2						
				NEW	RESEARCI	H APPLIC	ATION				
No.	MECID.No	Project Title	Applicant	Date of application	Approval SMEC	Approval HOD	Approval CIC	Approval Director	Approval CMEC	Status	
1	20143-2	Test research 2014	NOR 'ALIA BINTI RAMLAN	3/3/2014 3:31:17 PM	V	\checkmark	V		O	Kelulusan CMEC-Table for meeting	view
				DREVIO			ICATION				
		Ducie at		PREVIO	US RESEA						
No.	MECID.No	Title	Applicant	application	SMEC	HOI	D C	roval A IC I	pproval Director	CMEC	Status

	TABLE FOR MEETING	
Status	: Approve	4
Comment	Do not Approve Return to applicant :	_
Date of Meeting		

8.0 User Manual for Committee Members

8.1 Committee Members (UMMC/FOM Staff)

2

Login to <u>my.ummc.edu.my</u>

Notifikasi
Aduan Pelanggan (18)
Edms (29)
Harta (2)
Kehadiran (3)
Laporan Insiden (5)
Latihan/kursus (9)
Luar Negara (1)
Penyelidikan (Ethics) (1)
Tuntutan (76)

Senarai Permohonan Penyelidikan Yang Perlu Disahkan

Committee Review(1) <-----

	NEW RESEARCH APPLICATION										
No.	MECID.No	Project Title	Applicant	Date of application	Approval HOD	Approval CIC	Approval Director	Approval SMEC	Approval CMEC	Status	
1	20143-10	Medical research 05032014	NOR 'ALIA BINTI RAMLAN	20/01/2014 15:07:16Y	×	\checkmark	-	~	\checkmark	Kelulusan CMEC-Table for meeting	view

	PREVIOUS RESEARCH APPLICATION									
No.	MECID.No	Project Title	Applicant	Date of application	Approval SMEC	Approval HOD	Approval CIC	Approval Director	Approval CMEC	Status

	COMMITTEE REVIEW)
Comment :		4
	SUBMIT RESET	J

8.2 Committee Member (NON UMMC/FOM Staff)

Login to eservices.ummc.edu.my/iresearch



Notification :



NEW RESEARCH APPLICATION]
No	. MECID.No	Project Title	Applicant	Date of application	Approval HOD	Approval CIC	Approval Director	Approval SMEC	Approval CMEC	Status		
1	20143-10	Medical research 05032014	NOR 'ALIA BINTI RAMLAN	23-Jan-14 4:13:42 PMY	×	V	-	~	~	Kelulusan CMEC Table for meeting	view	← 3
DEVICUS RECEARCH ADDITION												
No	. MECID.No	Project Title Ap	oplicant D app	ate of lication	Approval SMEC	Approv HOD	al Appro	oval A C C	pproval Director	Approval CMEC	Status	
					COMMITTE	E REVIEW						
Con	nment	:										4
					SUBMIT	RESET						J