United Arab Emirates
Ministry of Health
Research Ethics Review Form

(For all research projects, except Randomized Control Trials
and student research projects)

For Research Office Use only

Application No. _____ Date of receipt:: _____

Meeting No:. _____ Date of Meeting: _____

Result: [ ] Approved [ ] Conditional approval (minor changes required)

[ ] Major changes required, resubmission to committee required after changes

Other outcomes: _____

_____

Instructions:

This form is applicable to all research projects except student research projects for academic purpose and for Randomized Control Trials. Please use another form for RCTs and student research.
Please fill all sections of the application form clearly.
Please read attached instructions carefully before filling the form.
Projects cannot be started before getting ethics approval. Please keep the start date of the projects, at least two months after the date of submission to the ethics committee.

Start and end dates of project: from: _____ to _____

Start and end dates of data collection/field work: from _____ to _____

Duration of study:

Does the objective of this research involve evaluation of a medical product (self therapy, biological product, medical drug or a medical device)?

[ ]Yes [ ] No

If Yes is the product registered to MOH UAE?

[ ]Yes [ ] No

If No was it approved by Drug registration and Control Department MOH UAE?

[ ]Yes [ ] No

If No did you get approval from Drug Registration and Control Department MOH for the product to be used as an investigational product?

[ ]Yes [ ] No

If Yes please attach the approval.

If No please refer to Drug Registration and Control Department for approval.

Section A: Research Details

Project Title: _____

_____

Principal Investigator:

Name:		
Position:		
Institution:		
Address:		
P.O. Box		City/Emirate:
Telephone No.:		Fax No.:
Email:		

Co investigators:

Name	Dept./Unit/Institution/Other	

I, hereby submit this study for the approval of the ethics committee and certify that I am responsible for the contents and information provided in this form.

	Name, Qualifications	Signature
Principal Investigator		
Departmental Chairman/Institution Director		

Section A: Trial Information	
A – 1 Title of Clinical Trial	
A – 2 Protocol ID Number: Protocol Date:	
A – 3 Phase of Trial to be conducted: [ ] Phase Three [ ] Phase Four (attach approval of reference bodies on phases 1 and 2)	
A – 4 Type of sponsorship	

[ ] Pharmaceutical company initiated study

Name of Pharmaceutical company

[ ] Investigator initiated study

Name of Investigator

A – 5 Therapeutic Area	
A – 6 Disease Type	

A – 7: Scope of the trial

[ ]	Diagnosis	[ ]	Pharmacodynamics
[ ]	Prophylaxis	[ ]	Bioequivalence
[ ]	Therapy	[ ]	Dose response
[ ]	Safety	[ ]	Pharmacogenomic
[ ]	Efficacy	[ ]	Pharmacoeconomic
[ ]	Pharmacokinatics	[ ]	Others: _____

A – 8a Age Span	[ ] Less than 18 years If yes specify: [ ] In Utero [ ] Preterm new born infants (gest. age ≤ 37 weeks) [ ] Newborn (0 – 27 days) [ ] Infant and toddler (28 days – 23 months) [ ] Child (2 – 11 years) [ ] Adolescent (12 – 17 Years)	[ ] 18 to 65 years	[ ] Above 65 years

A – 8b:

Gender [ ] Male [ ] Female

A – 8c:

Type of subjects [ ] Healthy volunteers [ ] Patients

A – 8d

Specific vulnerable populations:

[ ] Women of child bearing age
[ ] Pregnant females
[ ] Nursing females
[ ] Subjects incapable of giving consent personally
[ ] Others: _____

A – 8e
Type of Blinding:

[ ] Single Blinded
[ ] Double Blinded
[ ] Open Label
[ ] Other: _____

A – 8f

Randomization

[ ] Randomized
[ ] Non-randomized

A – 8g
Involves concurrent use of:

[ ] Placebo
[ ] Comparator Drug
[ ] Concomitant Drug
[ ] Not applicable (does not involve the use of placebo, comparator or concomitant drug).

A – 8h
Biological samples:

[ ] Blood or blood products
[ ] Tissue
[ ] Others: _____

A – 9 No. of study products used	Product Name: If drug product, please type INN Name: If Medical Device, please specify the class:
A – 10	Product Name:

Number of comparator products used	If drug product, please type INN Name: If Medical Device, please specify the class:
A – 11 Study drug administration schedule: [ ] Single Dose [ ] Multiple Dose [ ] Cyclical Dose [ ] Others, Please specify in section A - 12	Duration of study drug dosage / Treatment [ ] For multiple or cyclic dose, state treatment period: [ ] Days [ ] Weeks [ ] Years [ ] Continuous treatment until disease progression or unmanageable toxicity Describe if necessary in section A – 12
A – 12 Duration of follow-up post dosing of study drugs	[ ] Days [ ] Weeks [ ] Years Others, lease describe: _____
13 – Trial Center	
A – 13a Location of Trial Center	[ ] UAE Only [ ] GCC [ ] UAE/International
A – 13b Number of trial centers in the UAE	[ ] Single Center [ ] Multi center: state number: _____ Location 1: _____ Location 2: _____ Location 3: _____ Location 4: _____
A – 13c Duration of study in UAE	Start date: _____ End date: _____
A – 14 Is there a data safety monitoring committee for this study?	[ ] Yes [ ] No Name of main monitor: _____
A – 15a Study Hypotheses	
A – 15b Primary Objectives	

A – 15c Secondary objectives	
A – 15d Is there a sub-study involved?	[ ] Yes [ ] No If yes, please provide the title of sub study and its objectives.
A – 16a List the principal inclusion criteria	
A – 16b List the principal exclusion criteria	
A – 17 Data Analyses	Has a biostatistician been consulted? [ ] Yes [ ] No If yes, please provide the name and affiliation of biostatistician. If not, how will the data be analyzed?

Section – B: Type of therapeutic product under investigation	
B – 1 The product is of chemical origin?	[ ] Yes [ ] No
B - 2 The product if of biological / biotechnological origin?	[ ] Yes [ ] No
B – 3 Cell therapy medicinal product?	[ ] Yes [ ] No
B – 4 Gene therapy medicinal product?	[ ] Yes [ ] No
B – 5 Radiopharmaceutical medicinal product?	[ ] Yes [ ] No
B – 6 Immunological medicinal product (vaccines, allergens etc.)	[ ] Yes [ ] No
B – 7 Plasma derived medicinal product?	[ ] Yes [ ] No
B – 8 Other extractive medicinal product?	[ ] Yes [ ] No
B – 9	

Herbal medicinal product? B – 10 Homaopathic medicinal product? B – 11 Medicinal product containing genetically modified organisms? B – 12 Medical device	[ ] Yes [ ] No [ ] Yes [ ] No [ ] Yes [ ] No [ ] Yes [ ] No
If drug product, please fill section C If blood product, please fill section E If medical device, please fill section F	

Section C: Study Drugs to be Investigated		
Study Drug	1	2
C – 1 Active ingredient/Generic name or any code designation		
C – 2 Brand name (if any)	[ ] Not applicable	[ ] Not applicable
C – 3 Dosage form		
C – 4 Strength		
C – 5 Route of administration		
C – 6 Pharmacological class		

C – 7
Class of Study Drug

Class I New investigational drug without any clinical trial conducted yet
Class II New investigational drug with ongoing phase 1, 2 or 3 clinical trials
Class III Approved drug undergoing clinical trials for new indications, method of administration and/or dosage etc.
Class IV Approved drug whereby a marketing authorization has been granted and use in this trial as a study drug
Class V comparator drug or concomitant drug for approved indications, using approved method of administration and dosage etc.

C – 8	[ ] Class I [ ] Class II [ ] Class III [ ] Class IV	[ ] Class I [ ] Class II [ ] Class III [ ] Class IV
C – 9 For class III and IV study drugs, state the countries in which the		

drug has been granted marketing authorization		
C – 10 For product registered in the UAE, provide the product registration number	[ ] Not applicable	[ ] Not applicable
C – 11 Manufacturer of active ingredient	Name: Address:	Name: Address:
Section D: Comparator drugs to be used in the clinical trial		
[ ] Not applicable, check box if no comparator drug is used.		
Study Drug	1	2
D – 1 Active ingredient/Generic name or any code designation		
D – 2 Brand name (if any)	[ ] Not applicable	[ ] Not applicable
D – 3 Dosage form		
D – 4 Strength		
D – 5 Route of administration		
D – 6 Pharmacological class		
D – 7 Class of study drug	[ ] Class I [ ] Class II [ ] Class III [ ] Class IV	[ ] Class I [ ] Class II [ ] Class III [ ] Class IV
D – 9 For class III and IV study drugs, state the countries in which the drug has been granted marketing authorization		
D – 10 For product registered in the UAE, provide the product registration number	[ ] Not applicable	[ ] Not applicable
Section E: Biological / Biotechnological Investigational Medicinal Products Including vaccines		

E – 1 Type of product
E – 2 Extractive [ ] Yes [ ] No
E – 3 Recombinant [ ] Yes [ ] No
E – 4 Vaccine [ ] Yes [ ] No
E – 5 GMO [ ] Yes [ ] No
E – 6 Plasma derived products [ ] Yes [ ] No
E – 7 Others: _____

Section EA: Somatic cell therapy investigational medicinal product (No genetic modification)

EA – 1a Origin of cells
EA – 1b Autologous [ ] Yes [ ] No
EA – 1c Allogenic [ ] Yes [ ] No
EA – 1d Xenogeneic [ ] Yes [ ] No
EA – 1e If yes, specify the origin:

EA – 2 Type of cells
EA – 2a Stem cells [ ] Yes [ ] No
EA – 2b Differentiated cells [ ] Yes [ ] No
EA – 2c If yes, specify the type (keratinocytes, firbroblasts, chondrocytes etc.)
EA – 2d If others, please specify:_____

Section EB: Gene Therapy Investigational Medicinal Products

Section F: Study medical Devices to be Investigated

Name of Medical Device	
Class	
Description of Device	

Section G: Information about Placebo (if applicable)

[ ] No Placebo used

G – 1
Placebo number: _____
G – 2
Pharmaceutical form: _____
G – 3
Route of administration: _____
G – 4
Composition (apart from the active substances):
G – 5
Major ingredients:

Section H: Concomitant Drugs to be used in the clinical trial	
[ ] No applicable (No concomitant drug used)	
H – 1 Name of Concomitant Drug:	
H – 2 Active Ingredient / Generic name / code number:	
H – 3 Brand name (if any):	
H – 4 Dosage form:	
H – 5 Strength:	
H – 6 Route of administration:	
H – 7 Pharmacological class:	
H – 8 UAE Product registration number (if any):	
Section I: Information about local trial centers, Principal Investigators and Responsible IRB/REC: (Fill another sheet if more than one centers are involved)	
I-1 Name of Principal Investigator:	
I – 2 Certification Type:	
I – 3 Name of Body who issue the certificate:	
I – 4 Areas of specialty:	
I – 5 Place of practice:	
I – 5a Department	
I – 5b Address of practice:	
I – 6 Designation	
I – 7 Telephone number:	
I – 8 Fax number:	

I – 9 Email:	
I – 10 Name of trial center:	
I – 11 Address of trial center (if different from above)	
I – 12 Planned number of trial subjects:	[ ] [ ] [ ] [ ]
Section J: Information about local Contract Research Organization (CRO) If there are more than one CROs involved, please fill another sheet	
J – 1 How many CROs are involved in this project	[ ]
J – 2 Company Name:	
J – 2a Company address:	
J – 2b Telephone Number:	
J – 2c Fax number:	
J – 2d Please list the type of services engaged and provided in the following information	[ ] Monitoring [ ] Project management [ ] Data Management [ ] Laboratory [ ] Others: _____
J – 2e Is the local CRO authorized to act as the local sponsor for this clinical trial?	[ ] Yes [ ] No
Section K: Information about Local Sponsor	
K – 1a Name of Local Sponsor	
K – 1b Name of International Sponsor	
K – 1c Address of local sponsor	
K – 1d Telephone number:	

K – 1e Fax number:	
K – 1f Local company registration number:	
K – 1g Name of contact person:	
K – 1h Designation of contact person:	
K – 1i Telephone number:	
K – 1j Fax number:	
K – 1k Email:	
K - 2	Information about witness
K – 2a Name of contact person:	
K – 2b Designation of contact person:	
K – 2c Telephone number:	
K – 2d Fax number:	
K – 2e Email:	
K3	Insurance Company
K – 3a Name of Insurance Company	
K – 3b Limit of compensation	
Section L: Monitor / Monitoring Committee information	
L – 1 Name of main monitor:	
L – 2 Certification type:	
L – 3 Name of certificate	

issuing authority:	
L – 4 Address of issuing authority:	
L – 5 Telephone number:	
L – 6 Fax Number:	
L – 7 Email:	

Please fill in the information and send it back to us at **research.proposal@moh.gov.ae**