**proposal Application**

**doh-Ma’an 2025-2026 grant CYCLE**

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**TERMS OF REFERENCE**

We welcome applicants to apply for the 2025-2026 DOH-Ma’an Research Grant by submitting proposals to the DOH. The *terms of reference* pertaining to the 2025-2026 DOH-Ma’an Research Grant are given below:

1. If the proposal is selected, then it would be mandatory for the research project to be approved by BOTH the local IRB and the DOH IRB (ADHRTC).

1. All types of medical research proposals can be submitted including clinical trials, observational studies (diagnostic studies, prediction models, real-world evidence etc.)
2. Research proposals on all 3 areas of medical innovation are allowed to be submitted: (a) Drug(s) (b) Device(s), and (c) Artificial Intelligence software [with or without medical device]. A proposal can have a combination of any of the above.
3. Animal only studies will not be accepted, however, translational research is accepted.
4. First-in-human trials are allowed on patients with potentially fatal diseases.
5. First-in-human trials are not allowed on healthy subjects.
6. Each proposal will undergo at least 3 approval processes. Approval from the DOH’s Scientific Committee, DOH’s IRB, and DOH-Ma’an Steering Committee.
7. The DOH Scientific Committee will automatically forward the selected proposals to the DOH’s IRB, therefore the applicants will not need to apply separately to seek DOH IRB approval. If a proposal is already approved by the DOH IRB, then it would still be acceptable to be submitted for grant funding. Similarly, if the proposal already has a local IRB approval (with or without DOH IRB approval), then it would still be acceptable to be submitted for grant funding.

1. Public-private partnerships are allowed for joint proposals.
2. International partnerships are allowed and encouraged, especially with the global leaders in the field and/or with top medical institutions globally.
3. Applications will be scored based on many variables, but the highest scoring parameters include scientific merit (including background research and hypothesis), and the impact on the population of the UAE. The DOH-Ma’an Scientific Committee will be composed of scientists and physicians from different institutions.
4. Priority areas for the applications are well defined, along with a sample question, as given on the DOH-Ma’an Grant Webpage. Proposals which clearly fall under one of the priority areas will be scored higher for selection.
5. A detailed budget with a breakdown of the direct and indirect costs (overheads) will be needed for the grant proposal. If more than one institution is involved, then a detailed distribution of the budget between different institutions must be submitted. The distribution of budget internally within the parties (institutions) will *not* affect the scientific merit. In the detailed budget, FTE component must be highlighted if applicable.
6. If a patent is involved with innovation, then the IP (intellectual property), its division or split (if applicable), must be mentioned in the proposal. We encourage all applicants to register their patent(s) in the Abu Dhabi DED (Takamul) via the TAMM. It is not mandatory to have a patent registered at the time of the application. Having a patent registered (if applicable) will *not* affect the scoring for grant selection. The prototype/MVP/drug/device/AI software can be registered at more than one jurisdiction (e.g. Takamul, EPO, US-PTO etc.)
7. All DOH licensed healthcare providers can apply for the grant. This includes pharmacists, physicians, nurses, social workers, physical therapists, psychologists etc.
8. The Primary Investigator (PI) must be a full-time employee of a DOH licensed healthcare facility (a hospital or clinic). Co-PIs or co-investigators may be from any type of institution, including universities, private companies etc. and may be based internationally.
9. Progress reports must be submitted on the timelines as indicated at the acceptance of the grant.
10. Each selected proposal would receive funding but it may be distributed in 2 or more payments. If a research project requires additional funding, then the PI or PI’s institution would be responsible for provision of additional funds for the entire project. Additional funding from third parties is allowed (but must be detailed in the research proposal).

1. The study can continue for more than one year, however, this would be a one-time commitment from DOH-Ma’an.
2. Once the study is complete, acknowledgement of the DOH and Ma’an is mandatory in professional meeting abstracts, professional meeting presentations, and in peer-reviewed publications. The publication(s) must be submitted as an open-source publication in a peer reviewed journal.
3. Following documents along with filled IRB form must be submitted:
	* Research Personnel (all investigators) CV(s)
	* Valid ICH/GCP certificates of all investigators
	* Detailed Research proposal/protocol
	* Data Collection Sheet or eCRF (if applicable)
	* Informed consent form, both in English and Arabic (if applicable)
	* Intellectual property information (if applicable)
	* Insurance Certificate for the subjects enrolled in clinical trials (if applicable)
	* Detailed budget with overhead costs (if applicable). OPEX and CAPEX must be submitted separately (if applicable).
	* Material transfer agreement(s) between institutions (if applicable)
	* Contracts, MoU, NDA, CDA etc. with partnering institutions (if applicable)
	* CRO license (if applicable)
	* Other documents (if applicable, based on the study type)
4. Priority areas are given below, and a particular project may be applicable in more than one priority area:
5. In vivo and Ex-vivo Cell & Gene Therapy (including regenerative medicine, CAR-T cells, NK-CARs, gene editing [CRISPR-cas9, base editing, prime editing, etc.], TIL, MSC, iPSC, VST, etc.)
6. Omics (Genomics, Transcriptomics, Proteomics, Epigenomics, Metabolomics, Phenomics, Microbiome, etc.) & Precision Medicine (including organoid models)
7. Neurodegenerative and Neuroinflammatory Diseases (including Alzheimer’s, Parkinsons, multiple sclerosis etc.)
8. Cancer diagnostics and therapeutics (includes drug development, radioistotopes, molecular and omics [see “b” above] testing, etc.)
9. Behavioral Health and People of Determination (POD) [including all psychiatric/psychologic and neuropsychiatric conditions, including MDD, PTSD, GAD, OCD, ASD etc.]
10. Public Health & preventive Medicine (including pandemics, epidemics, endemics)
11. Innovation in health span and biology of aging (including diet, supplements and behavior)
12. Smart Hospitals/clinics and telemedicine (including IOMT, AI, blockchains, and other healthcare technologies)
13. Metabolic syndromes (including diabetes and obesity)
14. Reproductive Biology, fertility loss, and embryology.
15. Studies targeting fundamental hallmarks of Aging

# 1. Application Form (REC 001)

| **Yes** | **No** | **N/A** | **Checklist** | **Comments** |
| --- | --- | --- | --- | --- |
| **[ ]**  | **[ ]**  | **[ ]**  | “Proposal Application for Research Involving Human Participants” (DOH-IRB F001) is completed, signed and dated by the Principal Investigator and the Co-Investigators? |       |
| **[ ]**  | **[ ]**  | **[ ]**  | “Research Proposal Form” (DOH-IRB F002) is completed, signed and dated by the Principal Investigator? |       |
| **[ ]**  | **[ ]**  | **[ ]**  | Signed and dated “Curriculum Vitae” for each senior personnel in the research project are attached in the appendix to the Research Proposal Form? |       |
| **[ ]**  | **[ ]**  | **[ ]**  | Valid “Good Clinical Practice” (GCP) for each clinical personnel in the research project, Valid “Good Laboratory Practice” (GLP) for each clinical personnel in the research project are attached to the Research Proposal Form? (If applicable) |       |
| **[ ]**  | **[ ]**  | **[ ]**  | “Informed Consent Checklist” is attached? (if applicable) |       |
| **[ ]**  | **[ ]**  | **[ ]**  | If the study is Clinical Trial: appropriate “Informed Consent Forms” are filled, signed and attached? |       |
| **[ ]**  | **[ ]**  | **[ ]**  | If the proposal is omics or genomics studies: appropriate “Informed Consent Forms” (REC) is filled, signed and attached? |       |
| **[ ]**  | **[ ]**  | **[ ]**  | If the study is sponsored from a pharmacological or medical industry company, is the agreement or contract or MoU or NDA or CDA or other relevant document attached? |       |
| **[ ]**  | **[ ]**  | **[ ]**  | If the includes the use of artificial intelligence, data analysis, computed analysis of EHR or EMR data, are relevant documents for cybersecurity (if applicable) attached? |       |
|  |
| **Principal Investigator** First name:Middle name:Last name: |
|  |  |
| Signature*: (electronic signature is accepted)* | Date*(Day/Month/Year e.g. 01/OCT/2024)* |

# 2. Research Proposal Form (REC 002)

## SECTION I: GENERAL INFORMATION

|  |
| --- |
| 1. **Study type (*MORE THAN ONE CATEGORY MAY BE SELECTED):***
 |
| * + Multicenter study within UAE
	+ Multicenter study in UAE and internationally
	+ Interventional clinical trial (includes all phases of clinical trials: either device or drug or both)
	+ Pharmaceutical or Biotech or Technology company sponsored study
	+ Genomics-related research
	+ First-in-human trial
	+ Artificial Intelligence Study (e.g. computer vision, NLP [Gen AI], deep learning, etc.)
	+ Research involving vulnerable populations
	+ Other (you need to specify below)
		- ………………………………………………………………………………………………………………………………….
 |
| 1. **Methodology based type of research *(MORE THAN ONE CATEGORY MAY BE SELECTED)***
 |
|

|  |  |
| --- | --- |
| Prospective Registry  |  [ ]  |
| Retrospective Chart Review | [ ]  | Device Study | [ ]  |
| Artificial Intelligence Study (with or without a device) | [ ]  | Clinical Trial, if yes | [ ]  |
| Health Related Survey | [ ]  | Phase I [ ]  Phase II [ ]  Phase III [ ]  Phase IV [ ]  |  |
| Pragmatic study or comparative effectiveness trial | [ ]  | Others: (please specify below)…………………………………………………………………………………… | [ ]  |

 |
| 1. **Detailed Research Proposal**
 |
| * 1. Detailed Research Proposal/protocol is submitted
		+ It must cover all details related to the proposed research such as background, hypothesis, objectives, methodology, sample collection process, consenting process (may have more than one consent), recruitment process, data handling, cybersecurity, statistical analysis, future publications, patents, and any other related matter(s).
 |
| 1. **Research Site:**

Study sites that will be involved in any aspect of the research (whether data analysis, sample processing or analysis or recruitment of patients) |
| **Site (s)** | **Agreement in place**  |
|  | □ |
|  | □ |
|  | □ |
|  | □ |
|

|  |
| --- |
| 1. **Study title:**
 |
|  |
| 1. **Contact information:**
 |
| 1. ***Principle investigator (PI):***
 |
| **Name (first, middle, last)** |  |
| **Nationality**  |  | **Department/ Hospital** |  |
| **Mobile No (including country code)** |  | **DOH License #** |  |
| **Official E-mail** **(personal emails are not accepted)**  |  |
| **PI Professional Status** | □ Undergraduate student | □ Hospital Staff |
| □ Graduate Student/Post-Doctoral | □ University Faculty |
| □ Resident/Fellow | □ Other (specify)……………………………………………….. |
| **Professional Title** |  |
| 1. ***Co-Investigators and Members of Research Team (please add a separate document if more investigators)***
 |
| **Name** | **Email Address****(personal emails are not accepted)** | **Department/Hospital** | **Exact role in project** |
|  |  |  |  |
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| 1. **Study Duration**
 |  |
| **Total expected Study duration** |  |
| **Study expected start date** *(Day/Month/Year e.g. 20/JAN/2024):* | --/--- /---- |
| **Study estimated completion date** *(Day/Month/Year e.g. 20/JAN/2024):* | --/--- /---- |

 |

## SECTION II: COLLABORATING INSTITUTIONS/FACILITIES AND OTHER REC REVIEWS

|  |
| --- |
| **Is the proposed research will be done in collaboration with other collaborating institutes?**  |
| **□** Yes (if yes, skip to section III) | **□** No  |
| If you are collaborating with other sites, provide the name of each institution/facility and describe the type of involvement of each institution (e.g. recruitment, enrolment, consenting, study procedures, follow-up, and data analysis). Indicate if REC approval/site permission is attached |
| **National/local Collaboration** |
| **Institution Name** | **Describe Involvement** | **Local REC/IRB approval Attached? (Y/N)**  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| **International Collaboration** |
| Will any aspect of the study take place outside UAE?If yes, complete the table below. | **□** Yes | **□** No  |
| **List Location(s)** | **Name of Collaborating Institution/Facility/Hospital** | **Describe Involvement** | **REC/IRB approval attached?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## DOH research grant application form

|  |
| --- |
| **Proposal Budget Summary\* (all values in AED)** |
| **Year One Requested Funds** |  | **Total Requested Funds** |  |
| Year One Cash Cost Share |  | Total Cash Cost Share |  |
| Year One In-kind Cost Share |  | Total In-kind Cost Share |  |
| Year Two Cash Cost Share |  | Total Cash Cost Share |  |
| Year Two In-kind Cost Share |  | Total In-kind Cost Share |  |
| Year Three Cash Cost Share |  | Total Cash Cost Share |  |
| Year Three In-kind Cost Share |  | Total In-kind Cost Share |  |

\*Please submit the detailed OPEX and CAPEX separately.

|  |
| --- |
| **Additional Researchers / Collaborators / Industry Partners** |
| **Name** | **Role** | **Institution** | **Email** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |
| --- |
| **Signatures** |
| Primary Institution’s Representative\* Name (first, last) |  |
| Title |  |
| Official Email |  |
| **Institutional Representative Signature** |  |

(Electronic signatures are allowed)

\*Could be a C-suite member including the CEO, the Research/academic lead or Research Director, or other person in leadership at the institution

## SECTION III: FUNDING INFORMATION

|  |  |  |
| --- | --- | --- |
| 1. Would the study have additional funding besides the DOH-Ma’an Grant?
 | **□** Yes | **□** No  |
| 1. If yes, please specify:
 |
| **Funding agency**  |
| □ Governmental funding within UAE (besides DOH-Ma’an) |
| □ Private sector funding within UAE |
| □ International government funding  |
| □ International private sector funding  |
| □ International non-for-profit institution funding |
| □ Others |
| **Total budget of the project**: |  |
| **Percentage of budget split between institutions or companies (if more than one institution)**  |  |

\* In addition to DoH Research & Innovation Grant this application is filed for

## SECTION IV: DRUGS/BIOLOGICAL PRODUCTS/DEVICES, BIOLOGICAL SAMPLES, GENETIC TESTING, RADIATION and RADIOISOTOPES, AND EXPERIMENTAL ANIMALS

**Does the Proposal involve the use of any of the following? Check all that apply:**

|  |
| --- |
| 1. **Study intervention (*MORE THAN ONE CATEGORY MAY BE SELECTED):***
 |
| * An investigative/unapproved drug, supplement, chemical, biological products, or controlled substances
 | **□** Yes | **□** No  |
| * A medical or non-medical device
 | **□** Yes | **□** No  |
| * A placebo
 | **□** Yes | **□** No  |
| If “yes” to medical or non-medical device, then please complete ***PART 3*** below |
| 1. **Biological Samples (*MORE THAN ONE CATEGORY MAY BE SELECTED):***
 |
| Biological Samples will be collected (**Either from a biobank or prospectively obtained):*** + **Hematopoietic**
		- Peripheral blood
		- Umbilical cord
		- Hematopoietic stem cells from bone marrow
		- Hematopoietic stem cells collected from peripheral blood
		- Blood byproducts:
			* serum
			* plasma
			* buffy coat
	+ **Biofluids:**
		- Urine
		- Sputum
		- Saliva
		- Bile
		- Semen
		- CSF
		- Organ based: e.g. ocular, vaginal, ear, GI, skin etc.
	+ **Tissue or cells state**
		- Fresh
		- Frozen
		- Fixed
		- Processed
	+ **Human primary cells derived from human biosamples** (including iPSCs)
	+ **Nucleic Acids:** DNA or RNA derived from individual donors
	+ **Surgical Specimens**
 | **□** Yes\*\*all collected samples to be highlighted | **□** No  |
| If “Yes”:* Confirm that all relevant personnel have been **trained** and have experience in dealing with biological samples.
* Confirm that all relevant personnel have completed a “Blood borne pathogen training and immunization course”, which is valid for the study duration involving samples
 | **□** Yes**□** Yes | **□** No**□** No  |
| 1. **Genetic Material Testing**
 |
|

|  |
| --- |
| Genetic testing of biological samples (Blood, Urine, Tissue, Saliva, etc., or the use of recombinant DNA/Human gene transfer (including use of vectors) |

 | **□** Yes | **□** No  |
| If “Yes”: 1. **Specify the genetic test(s) to be performed on the samples selected above. (GWS, RT-PCR, NGS, etc.)**
 | …………………………… |
| 1. **Will the genetic sample(s) be sent outside the UAE for analysis?**
 | **□** Yes | **□** No  |
| If “**Yes**”, please specify the site outside UAE where the analysis will be performed and provide justification……………………………………………………………………………………………………………………………………………If “**No**”, please specify the site within UAE where the analysis will be performed.…………………………………………………………………………………………………………………………………………… |
| 1. **Will results of genetic testing be reported to subjects?**
 | **□** Yes | **□** No | **□** NA |
| If “Yes”, the following conditions must be met:1. A specific genetic test is being performed and subjects are notified at the time of the consent what the test is and how the results might affect them.
2. Specify who will transmit the results of the study.
3. Genetic counsellors will be available to subjects and fully covered by the study
4. Specify pathway of what happens after reporting of a known pathogenic mutation which can confer a disease phenotype
 |
| 1. **Stem Cells, Zygotes, Gametes and Fetuses**
 |
| The Research project involves the use of stem cells, zygotes, gametes, or fetuses  | **□** Yes | **□** No  |
| If “Yes”, please complete the ***PART 4*** of the application form below  |
| 1. **Radiation or Radioisotopes**
 |
| The research project involves the use of Radiation or Radioisotopes | **□** Yes | **□** No  |
| If “Yes”: |
| * Please specify where exactly the radiation will be used (Hospital, and building / room no.):
 |  |
| * What is the half-life of the radioisotope (if applicable)
 |  |
| * Please specify Name(s) of approved radioisotope permit holder, and the duration of permit:
 |  |
| * Please specify methods of special handling and disposal of radioactive waste:
 |  |
| * Please specify whether the facility has approval of FANR-UAE
 |  |
| * Confirm that all relevant personnel have been **trained** and have an experience in dealing with radiation or safe handling of Radioisotopes.
 | **□** Yes | **□** No  |
| 1. **Gene Editing**
 |
| * Is any type of gene editing involved?
 | □ Yes | **□** No |
| * Is a vector used for gene editing?
 | **□** Yes | **□** No |
| * Is any ex-vivo gene editing required for the protocol
 | **□** Yes | **□** No |
| If any type of gene editing is required as per the study, then details of the gene editing method (e.g. TALEN, CRISPR, ZFN, Base editing, Prime editing, etc.), vector used (e.g. lentivirus, AAV, others), CMC processes, cGMP lab details, etc. will need to be detailed in the protocol.  |

## SECTION V: RESEARCH PROTOCOL AND SIGNIFICANCE

1. **Please provide the proposed project abstract including the following subheadings: Hypothesis, Objectives, methods, and potential risks (up to 1000 words). Please do not include introduction/background.**

|  |
| --- |
|  |

1. **Please describe briefly how this study will contribute to existing knowledge in the field and its impact on the population of the UAE and/or globally?**

|  |
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|  |

## SECTION VI: RISKS AND BENEFITS OF THE PROPOSED RESEARCH

|  |
| --- |
| 1. **POSSIBLE RISKS**
	1. **Indicate if the participants might experience any of the following risks:**
 |
| 1. Physical risk (including any bodily contact or administration of any substance)?
 | **□** Yes | **□** No  |
| 1. Psychological risks (including feeling demeaned, embarrassed, worried or upset etc.)?
 | **□** Yes | **□** No  |
| 1. Social risks (including possible loss of status, legal risk, privacy and/or reputation as well as economic risks, social media harassment etc.)?
 | **□** Yes | **□** No  |
| 1. Are any possible risks to participants greater than those the participants might encounter in their everyday life in your best judgement?
 | **□** Yes | **□** No  |
| 1. **If you checked yes for any questions i – iv above, please describe the risk(s) in the space below**
 |
| 1. **Management of Risk: describe how each of the risks identified above will be managed or minimized. Please include an explanation regarding why alternative approaches cannot be used.**
 |
| 1. **Misrepresentation/Trick: Is there any Misrepresentation/Trick involved in this research?**
 |  **□** Yes | **□** No  |
| 1. **If Misrepresentation/Trick is to be used in your methods, describe the details of the Misrepresentation/Trick (including what information will be withheld from participants) and justify the use of Misrepresentation/Trick.**

**In case of adverse event that require emergent medical attention due to the conduction of the experiment, it is the PI responsibilities to secure access to emergency services within a hospital/clinic setting either within the premise or within the vicinity nearby.** |
| 1. **POSSIBLE BENEFITS:**
 |
| Discuss any potential benefits to the scientific community/society that justify involvement of participants in this study. **(Please Note: Benefits should not be confused with compensation or reimbursement for taking part in the study).** |

## SECTION VII: PRIVACY AND CONFIDENTIALITY

|  |
| --- |
| 1. Will you or any member of your research team collect or have access to any of the personal identifiers (protected health information [PHI]) listed below? **□** Yes **□** No
2. If yes, select all that apply:
 |
| □ Name  | □ IP (Internet Protocol) Address |
| □ Date (All elements of dates [except year] for dates directly related to an individual, including birth date, admission date, discharge date, date of death etc.) | □ Biometric Identifiers (including retinal scans or fingerprints) |
| □ Current or previous home Mail address | □ Photos/Images |
| □ Home or Cell Phone # | □ Signatures, handwriting samples |
| □ Passport # of any country  | □ National ID # (expatriates) or Emirates ID # |
| □ Driving License (any country) | □ Official email address |
| □ Video recording with face (even from social media) | □ Personal email address |
| □ Vehicle ID (if more than one car ownership, then any vehicle ID) | □ Any audio recording with voice (including from social media)  |
| □ Medical record number (s) | □ Health insurance membership # |
| □ Patent number (filed in any country) | □ Any unique identifiers (in the best judgement of the investigators) not mentioned above |

## SECTION VIII: CONSENT PROCESS

|  |
| --- |
| **1. Is Informed Consent Required?**  |
| * Will you use a written informed consent document?

**□** Yes**□** No, I am asking a waiver of written informed consent**□** Not applicable |
| **□ English and Arabic consent forms must be submitted.** **□ Other languages to be provided if needed depending on the demographics of the studied population.**  |
| **2. Written Parental Permission – special consideration**  |
| * Will you obtain written parental or guardian permission for children, individuals under 18, prisoner(s), and incompetent?

**□** Yes**□** No, I am asking a waiver of written informed consent**□** Not applicable |

## SECTION IX: CONFLICT OF INTEREST DISCLOSURE (PLEASE READ CAREFULLY AND IF NOT SURE, THEN CONTACT DOH)

|  |
| --- |
| **The IRB policy requires that members of the team conducting research involving human participants at the institute(s) must disclose known significant financial or other interests that would reasonably appear to be affected by the research project; and that if the interest is deemed to constitute a conflict of interest with the proposed research, the conflict has to be managed prior to the faculty member’s engaged in the research with human participants** |
| **□** Yes | **□** No  | Are you, a first-degree family member, or spouse, the inventor of any products (including patents), novel treatment under evaluation, or technology used in the research? |
| **□** Yes | **□** No  | Do you, or does a first-degree family member, or spouse, have fiduciary role or have an ownership interest in any entity that provides materials, novel treatment under evaluation, products, technology, or services in the research? |
| **□** Yes | **□** No  | Do you or does any first-degree family member, or spouse receive(s) income/payments from an entity that provides materials, novel treatment under evaluation, products, technology, or services in the research? |
| **□** Yes | **□** No  | Is the research sponsored by a company for which you, and/or a first-degree family member consult, serve on its scientific advisory board, data safety monitoring board, or board of directors, or have any paid position? |
| **□** Yes | **□** No  | Is the research sponsored by a company for which you (or your spouse or your first-degree relatives) hold any ownership interest (stock, not including stock owned through a mutual fund) or from which you are entitled to receive royalties from a licensing agreement? |
| **□** Yes | **□** No  | Is the research sponsored by a *for-profit* company (partially or fully)? |
| **□** Yes | **□** No  | The value of my remuneration or financial interest exceeds AED 10,000 (annually) in the past 3 years with the company or entity involved in research? |
| **□** Yes | **□** No  | Are you, a first-degree family member, or spouse, receive other remuneration (trips, gifts…etc.) from company or entity involved in research? |

|  |
| --- |
| **What is (are) the name(s) of the company or entity (related to this research) for which you will be engaging in the external activity (if applicable)?**  |
| **Please provide a brief description of the nature of your relationship with the company or entity, and the amount of your expected remuneration from, or the value of your financial interest in the outside company or entity; if applicable.** |
| **Investigators must declare to the DOH IRB of any change in circumstances during the development of, or in the course of a project that would mean that they or their spouse, or first-degree family members would receive or hold any of the declarable items described above. Please check the following box if applicable.****[ ]  I have read the above statement on conflicts of interest. I have nothing to declare now, and I will immediately declare in writing to the DOH IRB of any future conflicts of interest**  |

## SECTION X: PRINCIPAL INVESTIGATOR CERTIFICATION

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| **I agree to:****Comply with the provision of the UAE federal law on the subject of medical liability, and its Implementing Regulations governing research on human subjects, any Ministerial terms, rules & procedures regulating research & medical trials protocol & standards issued by the DOH, and all other applicable UAE Federal Laws & Regulations, including but not limited to, UAE Federal Law No.2 of 2019; and Abu Dhabi Healthcare Information and Cyber Security [ADHICS] Standard.** **I also understand the absolute need to:**1. Design the study with the standards set by the DOH and other sponsoring agencies.
2. Obtain prior approval from the DOH IRB before amending the research protocol or the approved consent form.
3. Report to the DOH IRB in accordance with IRB policy or standard(s), any adverse event(s) and/or unanticipated problem(s) involving risks to participants.
4. Submit a progress report both annually and whenever requested by the DOH IRB.
5. Submit the Re-Approval form/Completion Form as needed.
6. Ensure that each individual listed as study personnel in this application is knowledgeable of the study procedures as in the study protocol and has a valid GCP certification.
7. Include the IRB approval # in any published paper coming out of this study.
8. Abide to the items and conditions listed in the attached files, including but not limited to the researcher guide, study proposal, informed consent, etc.
9. Abide timely with all the requested reports or forms, as failure to do so will entitle the DOH IRB to terminate the approval already granted to the study under progress.
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| **Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.**

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| **Principle Investigator (PI) Name****(first, middle, last)****---------------------------------------------** | **PI Signature****(electronic signature accepted)****----------------------------------------** | **Date (day/MON/year)****(e.g. 23/AUG/2024)****--------------------------------** |

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# 3. Device Use Form

**The IRB requires the fulfilment of the regulations below in all proposals involving the use of Devices (transponders, pumps, robots etc.):**

Please respond to the following points:

1. Identify anatomical site(s) where the device will be located (please also include the side)

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1. Describe the device. Identify any active ingredient(s)/chemical(s) (e.g. mercury, lead, alloys, etc.) contained in or with the device:

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1. What is the size (dimensions) of the device?

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1. Describe the method by which the device will be implanted (and experience of the person(s) performing the procedure):

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1. Will the device be eventually recovered/retrieved after the study? [ ] yes [ ] no

If yes, describe how the device will be recovered/retrieved:

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1. Will the device have the capability to capture/process/store/communicate healthcare data and outcomes? [ ] yes [ ] no

If yes, describe how the device will be capturing/processing/storing/communicate:

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1. Is the device approved by UAE authorities (e.g. MoHAP)? [ ] yes [ ] no

If yes, provide authorization details

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If no, provide details of any international authorization (e.g. USFDA, EMA, PMDA, MHRA, TGA, NMPA, etc.)

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If none of the above, provide additional details

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| Principal Investigator printed name (first, middle, last) |
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| Signature (electronic signatures accepted) | Date (dd/MON/year e.g. 23/SEP/2026) |
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#  4. Use of Stem cells, Zygotes, Gametes or Fetuses In Research Form

Please respond to the following points:

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| 1. Identify the exact stem cell source, and describe how you plan to acquire the bio-specimens (i.e. stem cells extracted from the umbilical cord or adult stem cells):
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| 1. Please describe the specific use and the rationale for the use of the stem cells:
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| 1. Do you plan to generate new Human embryonic stem cell (HESC) lines?
 | [ ] Yes [ ] No If “Yes”, please explain the scientific rationale for generating new Human embryonic stem cell (HESC) lines:………………………………………………………….. |
| 1. Where will the research take place? Identify all the spaces and locations, where the research will be performed. This includes ancillary support rooms such as tissue culture rooms and freezer storage areas (Indicate institute, and building, floor, and room number):
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| Please provide a list of all individuals involved in the design, conduct, or reporting of the research**:** |

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| Name | Department/Division | For renewals, is this individual new since the last submission? |
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**I, the principal investigator, confirm that I shall abide by the regulations set by the Department of Health regarding research on stem cells, zygotes, gametes and fetuses. I understand that no research may be conducted for the purpose of human cloning. I will abide by the prohibitions determined by medical liability law, regulations & resolutions in implementation thereof, and ethical principles, where harms and dangers to humanity outweigh the expected benefits. I certify that the research proposal is fulfilling the aforesaid law & regulations & the following conditions:**

1. Cloning of humans for the purpose of obtaining and using stem cells in research, or for any other use is strictly prohibited.
2. Excess fertilized eggs from in-vitro fertilization procedures performed for medical indications shall not be used for therapeutic purposes or in stem cell research.
3. Male or female gametes taken from sperms or eggs may not be donated to produce fertilized eggs that can grow into a fetus for the purpose of generating stem cells therefrom.
4. Embryonic stem cells derived from fetuses aborted in accordance with the provisions of the medical liability law & its implementing regulations, or from miscarried fetuses without any signs of life yet may be used whether in research or in scientific and laboratory experiments in accordance with applicable UAE federals and local rules.
5. In the case of stillborn fetuses, embryonic stem cells may be transferred and used in research in accordance with the law.
6. Somatic stem cells of an adult human may be used, provided the said human is not subject to any harm, and such stem cells can be used to treat a patient with a fatal disease, and the expected benefit outweighs the possible harm.
7. Research objectives shall be clearly and accurately defined, and the research is preceded by sufficient experiments on animals or organoids if the nature of the research so requires, subject to the decision of the DOH IRB.
8. Assessing the expected benefit for the human subject and the extent to which it outweighs the possible harm shall be through a clear and thorough scientific assessment conducted by the investigator and submitted to the DOH IRB.
9. If the DOH IRBfinds that the potential harm for the human subject outweighs the expected benefit, it shall not approve the research project.
10. The DOH IRBshall review periodic reports submitted by the investigator to ensure that the expected benefit continues to outweigh the possible harm.
11. The investigator or research team conducting the research shall be specialized and shall have sufficient prior scientific expertise (*specifically in conducting the stem cell/zygote/gamete or fetus clinical trial)* and scientific competence.
12. The "Informed Consent" shall be obtained from the human subject prior to conducting the research and the information provided shall contain a full explanation of expected benefits and potential risks of the research.
13. The investigator shall keep detailed records of the source of stem cells and results of their use in the research and shall submit periodic research reports to the DOH-IRB. The institution may set up its own bank to store stem cells for research purposes subject to the approval of the DOH IRB.
14. Stem cells stored in stem cell banks may not be used for research purposes without the prior permission of the DOH IRBand the owner's consent, and upon obtaining the "Informed Consent" from the donor.
15. Each sample shall be given a permanent label indicating to whom it belongs. Information included in the said label shall be updated by the principal investigator under the supervision of the DOH IRB.
16. The institution shall set up a special record for research conducted on the sample under the supervision and monitoring of the DOH IRB.
17. The institution shall safeguard the sample and shall destroy it under the supervision of the DOH IRBwhen it is no longer needed or if the donor so requests.
18. The institution shall prepare a periodic report on research conducted on the sample for submission to the DOH IRB.
19. The investigator shall submit, along with the research proposal, a description of the mechanism of safeguarding samples and records thereof.
20. All personal data resulting from the research conducted on the sample shall be part of the rights of the donor, and they may not be used or published without his consent, taking confidentiality and privacy into consideration.
21. The DOH IRBmay, when necessary, add or amend conditions for use of stem cells/zygote/gamete/fetus.

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| Principal Investigator printed name (first, middle, last) |
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| Signature (electronic signatures accepted) | Date (dd/MON/year e.g. 23/SEP/2026) |
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