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DEPARTMENT OF HEALTH

[RESEARCH APPLICATION FORM]

Contents

Note: These are mandatory for all projects submitted to local IRB Committee as full board review**.** To provide the following along with filled IRB form:

- Detailed Research proposal
- PI and Co-PI CV's & GCPs
- Consent Form (if applicable)
  - Informed Consent Forms must be provided in both Arabic and English languages, and both should have same text (descriptions).
- Data Collection sheet (if applicable)
- Survey/Questionnaire (if applicable)

1. Application Form (REC 001)

YES	NO	N/A	CHECKLIST	COMMENTS
☐	☐	☐	"Proposal Application for Research Involving Human Participants" (Form # REC 001) is completed, signed and dated by the Principal Investigator and the Co-Investigators?	
☐	☐	☐	"Research Proposal Form" (REC 002) 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?	
☐	☐	☐	"Informed Consent Checklist" (REC) is attached?	
☐	☐	☐	If the study is Clinical Trial: appropriate "Informed Consent Forms" (REC) is filled, signed and attached?	
☐	☐	☐	If the study is Medical/Scientific Research: appropriate "Informed Consent Forms" (REC) is filled, signed and attached?	
☐	☐	☐	If the proposal is genetics or genomics studies: appropriate "Informed Consent Forms" (REC) is filled, signed and attached?	
☐	☐	☐	If the study includes the use of stem cells: "Use of Stem Cell in Research" Form (REC) is attached in the appendix to the Research Proposal Form?	
☐	☐	☐	If the study includes the use of devices: "Devices Use" Form (REC) is attached in the appendix to the Research Proposal Form?	
☐	☐	☐	If the study includes the use of drugs and/or biological products: "Use of Drugs and/or Biological Products in Research" Form (REC) is attached in the appendix to the Research Proposal Form?	
☐	☐	☐	If the study is sponsored from a pharmacological or medical industry company, please attach relevant documents	
☐	☐	☐	If the includes the use of artificial intelligence, data analysis, computed analysis of EHR data, please attach relevant documents	

Principal Investigator Name _____

Signature _____ Date _____

2. Research Proposal Form (REC 002)

SECTION I: GENERAL INFORMATION

1- This study needs to be presented to ADHRTC because it is:

- ☐ Multi-center study;
- ☐ Clinical Trial study;
- ☐ Pharmaceutical sponsored study;
- ☐ Research with genetic material;
- ☐ Genomics-related research;
- ☐ Processing of medical data outside UAE for research purpose;
- ☐ Research that carries significant or potential risk to human subjects (patients);
- ☐ Other (you need to specify below)
  - ……..

2- Type of Research

Type of Research			
Audit	☐	Registry	☐
Retrospective Chart Review	☐	Device Study	☐
Case Report Review	☐	Clinical Trial, if yes Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐	☐
Health Related Survey	☐		
Post Marketing Observational Study	☐	Others: (please specify below) ……	☐

3- Detailed Research Proposal

- ☐ Detailed Research Proposal submitted
  - It must cover all details related to the proposed research such as objectives, methodology, sample collection process, consenting process, data handling and analysis and any related matter.
  - In addition to the documents listed in page 2

4- Research Site:
Study sites that will be involved in the research

5- Title of Study:

6- Contact information:			
a) Principle investigator (PI):			
Name			
Nationality		**Department/ Hospital**	
Mobile No.		**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) ……..	

b) Co-Investigators and Members of Research Team:

Name	Email Address	Department/Hospital	Role in Project

7- Study Duration	
Total expected Study duration	
Study expected start date (Day/Month/Year)	--/-- /--
Study estimated end date (Day/Month/Year)	--/-- /--
Study estimated completion date (Day/Month/Year)	--/-- /--
Retrospective study period (Day/Month/Year)	From --/-- /-- to --/-- /--

SECTION II: COLLABORATING INSTITUTIONS/FACILITIES AND OTHER REC REVIEWS

Will the research be conducted only at the premises of your institute with no involvement of a collaborating institution?	
□ 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 Collaboration

Institution Name	**Describe Involvement**	**REC Approval/Site Permission Attached?**

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/Ethics Approval and/or Site Permission Attached?**

SECTION III: FUNDING INFORMATION

1. Is this research being funded?	□ Yes	□ No
2. If yes, please specify:		
Funding agency		
□ Governmental funding within UAE		
□ Private sector funding within UAE		
□ International government funding		
□ International private sector funding		
□ Under graduate / post graduate student funding		
□ Does not required funding		
Total budget of the project:		

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. Drugs/ Device Use		
• An investigative/unapproved drug, supplement, chemical, biological products, or controlled substances	□ Yes	□ No
• A medical or non-medical device	□ Yes	□ No
• A proprietary product	□ Yes	□ No
• A placebo	□ Yes	□ No
If "Yes" to any of the previous points, please fill the REC form #3 for the use of Devices; AND the REC form #4 for the use of drugs and/or biological products in research.		
2. Biological Samples		
Biological Samples will be collected (**Either banked or prospectively obtained):** ○ Blood ▪ Peripheral ▪ umbilical cord ▪ blood byproducts:	□ Yes □ Yes □ Yes	□ No

• serum • plasma • buffy coat ○ Biofluids: ▪ Urine ▪ Sputum/Saliva ▪ Bile ○ Tissue or cells ▪ Fresh ▪ Frozen ▪ Fixed ▪ Processed ○ Human primary cells derived from human biosamples ○ Nucleic Acids: DNA or RNA derived from individual donors	□ Yes □ Yes □ Yes	
If "Yes": - Confirm that all relevant personnel have been **trained** and have an experience in dealing with biological samples. - Confirm that all relevant personnel have completed a "Blood borne pathogen training and immunization".	□ Yes □ Yes	□ No □ No
3. 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": **A. Specify the genetic test(s) to be performed on the samples selected above. (GWS, RT-PCR, …etc)**	……	
B. Will the genetic sample be sent outside the UAE for analysis?	□ Yes	□ No
If "**Yes**", please specify the site outside UAE where the analysis will be performed. …… If "**No**", please specify the site within UAE where the analysis will be performed. ……		
C. 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.** Specify whether genetic counsellors will be available to subjects.		

4. In case of "incidental genetic findings" not listed in the original consent form, the patient must be notified.		
4. Stem Cells, Zygotes, Gametes and Fetuses		
The Research project involves the use of stem cells, zygotes, gametes, or fetuses	□ Yes	□ No
If "Yes", please fill the REC form # 005 for the use of Stem Cell, Zygotes, Gametes and Fetuses		
5. Radiation or Radioisotopes		
The research project involves the use of Radiation or Radioisotopes	□ Yes	□ No
If "Yes":		
- Please specify where the radiation will be used (Hospital, and building / room no.):		
- 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:		
- Confirm that all relevant personnel have been **trained** and have an experience in dealing with Radiation or safe handling of Radioisotopes.	□ Yes	□ No
5. Experimental Animals		
The research project involves the use of Experimental Animals?	□ Yes	□ No
If "Yes", approval from the Local Animal Facility and from the REC/IRB, Approval should be obtained before the use of experimental animals is initiated. Please fill the REC form #? for Experimental Animal Use in research.		

SECTION V: RESEARCH PROTOCOL AND SIGNIFICANCE

1. **Please provide the proposed project abstract including the following subheadings: Background, objectives, and methods (not more than 300 words)**

2. **Please describe briefly how this study will contribute to existing body of knowledge in the field.**

SECTION VI: RISKS AND BENEFITS OF THE PROPOSED RESEARCH

1. POSSIBLE RISKS		
A. Indicate if the participants might experience any of the following risks:		
i. Physical risk (including any bodily contact or administration of any substance)?	□ Yes	□ No
ii. Psychological risks (including feeling demeaned, embarrassed, worried or upset)?	□ Yes	□ No
iii. Social/Professional risks (including possible loss of status, legal risk, privacy and/or reputation as well as economic risks)?	□ Yes	□ No
iv. Are any possible risks to participants greater than those the participants might encounter in their everyday life?	□ Yes	□ No
B. If you checked yes for any questions i – iv above, please describe the risk(s) in the space below		
C. 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.		
D. Misrepresentation/Trick: Is there any Misrepresentation/Trick involved in this research?	□ Yes	□ No
i. 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 setting either within the premise or within the vicinity nearby.		
2. 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 listed below? □ Yes □ No

2. If yes, select all that apply:

□ Name	□ IP Address
□ Date of Birth	□ Biometric Identifiers
□ Mailing or Email Address	□ Photos/Images/Audio Recording
□ Phone or Fax Numbers	□ Signatures, handwriting samples
□ National ID	□ Any unique identifiers not mentioned above
□ License, Certificate or Vehicle ID	

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

2. Informed consent – special consideration:

3. Written parental permission

- Will you obtain written parental or guardian permission for children, individuals under 18, prisoner and incompetent?
  - □ Yes
  - □ No, I am asking a waiver of written informed consent
  - □ Not applicable

4. Please attach/upload <u>English and Arabic</u> versions of the consent form (any other language that the committee deems necessary) .

Attached consent forms must be complying with DOH Consent Guideline.

5. Only for genetics, In case of Incidental genetic findings, you will be notified accordingly (statement for that)

SECTION IX: CONFLICT OF INTEREST DISCLOSURE

The REC policy requires that members of the faculty conducting research involving human participants at the institute must disclose known significant financial 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 family member, or spouse the inventor of any products, novel treatment under evaluation, or technology used in the research?
□ Yes	□ No	Do you, or does a 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 family member, or spouse receives 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 family member consult, serve on its scientific advisory board, data safety monitoring board, or board of directors or have a paid position?
□ Yes	□ No	Is the research sponsored by a company for which you (or your spouse or your children) 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 company?
□ Yes	□ No	The value of my remuneration or financial interest exceeds DH 10000
□ Yes	□ No	Are you, a family member, or spouse receive other remuneration (trips, gifts… etc.)

What is (are) the name(s) of the company or entity 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 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 REC 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 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 REC of any future conflicts of interest**

SECTION X: PRINCIPAL INVESTIGATOR CERTIFICATION

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 REC before amending the research protocol or the approved consent form.
3. Report to the REC in accordance with REC policy, 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 REC/DOH.
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 described in the proposal.
7. Include the REC approval no. 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 REC to terminate the approval already granted to the study under progress.

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

Principle Investigator (PI) Name	**PI Signature**	**Date**
---	---	---
Medical student/Student Investigator Name*	**Student Investigator Signature**	**Date**
---	---	---
Co-Investigator Name	**Co-Investigator Signature**	**Date**
---	---	---

*(Only for student, resident or fellow-initiated Research)

3. Devices Use Form

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

Please respond to the following points:

A. Identify anatomical site where the device will be located:

B. Describe the device. Identify any active ingredients/chemicals (mercury, etc.) contained with the device:

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

D. Describe the method by which the device will be implanted:

E. Will the device by recovered/retrieved? ☐yes ☐no

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

F. Will the device has 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:

G. Is the device approved by UAE authorities? ☐yes ☐no

If yes, provide authorization details

If no, provide details of any international authorization

If none of the above, provide additional details

4. USE OF STEM CELL, ZYGOTES, GAMETES AND FETUSES IN RESEARCH FORM

Please respond to the following points:

A- Identify the 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):

B- Please describe the specific use and the rationale for the use of the stem cells:

C- 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:

D- Where will the research take place? Identify all space 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):

E- Please provide a list of all individuals involved in the design, conduct, or reporting of the research**:**

Name	Department/Division	For renewals, is this individual new since the last submission?

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 case of stillborn fetuses, embryonic stem cells may be transferred and used in research in accordance with the law.
6- Stem cells of an adult human may be used, provided said human is not subject to any harm, and such stem cells can be used to treat a patient, 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 if the nature of the research so requires, subject to the decision of the REC/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 REC/IRB.
9- If the REC/IRB finds that the potential harm for the human subject outweighs the expected benefit, it shall not approve the research project;
10- The REC/IRB shall 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 scientific expertise 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 REC/IRB. The institution may set up its own bank to store stem cells for research purposes subject to the approval of the ADHRTC.

14- Stem cells stored in stem cell banks may not be used for research purposes without the prior permission of the REC/IRB and 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 said label shall be updated by the principal investigator under the supervision of the REC/IRB.

16- The institution shall set up a special record for research conducted on the sample under the supervision and monitoring of the REC/IRB.

17- The institution shall safeguard the sample and shall destroy it under the supervision of the REC/IRB when 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 REC/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 REC/IRB may, when necessary, add or amend conditions for use of stem cells.

1. Date:			
2. Study Title:			
3. Study Design:			
4. Principal Investigator (PI):			
College/Department:		PI Title:	
Phone:		Email:	
Fax:		Mailing address:	
Sponsor/Funding agent (NA: ☐):			
5. Total number of subjects:			
Note: The numbers below should reflect activity for the entire length of the project:			

5. Final Report (Study Completion or Termination) Form

Number of subjects planned:	Number enrolled:
Number of subjects completed:	Number of subjects discontinued:
Number of signed informed consent forms in your study file:	
6. Briefly summarize your project (an attached report/reprint will not replace this summary):	
7. If study was terminated, specify reason (NA: ☐**):**	

Report prepared by:

Printed Name	
Signature	Date

I have reviewed this report:

Principal Investigator Name:	
Signature	Date

6. IRB Committee Risk Assessment Form

Institution:	
Principal Investigator	
Project Title	

Summary of the project, to include its significance (max 300 words):

1. **Pharmaceutical sponsor trial** ☐ **Yes** ☐ **No (If not, go to #2)**

   a. The trial is:
   - ☐ Funded
   - ☐ Non-funded (e.g. material transfer, material loan, service support)

   b. If funded, payment is made to:
   - ☐ Institution
   - ☐ Principal Investigator
   - ☐ Not Applicable

   c. Team members who declare Conflict of Interest:
   - ☐ Nobody in the research team has a conflict of interest
   - ☐ Principal Investigator
   - ☐ Co-investigators
   - ☐ Other study team members

   d. Intervention & MOH importation license status (if needed):
   - ☐ Drug
   - ☐ Device
   - ☐ Other

   ☐ Public website listing, reference and data results (e.g. www.clinicaltrials.gov identifier NCT number).

   Locations:
   - ☐ Single center
   - ☐ Multicenter (list centers or attach listing)

2. **Multicenter clinical research** ☐ **Yes** ☐ **No (If not, go to #3)**

   a. Who is the record holder of the research?

b. Consenting process:

- ☐ Face-to-face
- ☐ Online
- ☐ Waiver of Inform Consent Form

c. Describe the Database used to store information, and its location:

d. Systems of Electronic Data collection

e. List participation sites. You may attach separate sheets if needed.

f. Contract/Agreement between parties

a. An agreement is in place ☐ Yes ☐ No

b. There are other UAE sites already involved ☐ Yes ☐ No

c. Data use agreement

- ☐ Material transfer
- ☐ Material loan
- ☐ Non-Disclosure Agreement
- ☐ Other

g. Data source for the records shared among the centers:

- ☐ Medical records
- ☐ **O**nline Case Report Forms & tests/results
- ☐ PHI (protected health information) shared with 3rd parties: tick all types applicable:
  - ☐ Name collected
  - ☐ Street address, PO Box, city collected
  - ☐ Date of birth collected
  - ☐ Date of death collected
  - ☐ Phone numbers collected
  - ☐ Fax number collected
  - ☐ Email address collected
  - ☐ Emirates ID # collected
  - ☐ Passport # collected
  - ☐ Medical record #
  - ☐ Account numbers (bank, credit cards, hospital) collected

- ☐ Certificate/license numbers (DOH, professional, driver's) collected
- ☐ Vehicle license, plate numbers collected
- ☐ Device identifiers (IP, Web URLs) collected
- ☐ Biometric identifier collected
- ☐ Full face photo or comparable images
- ☐ Unique identifying number, characteristic or code collected

List your reason for collecting the PHI indicated (ticked) above:

3. Genetics medical testing & genomics or genetics research utilizing non-commercially purchased DNA/RNA ☐ Yes ☐ No

a. Patient Genetics tests are proposed:
- ☐ Not Applicable, no patient genetics testing
- ☐ Single tests
- ☐ Multiple tests

b. In either medical testing or research, are vulnerable population involved as subjects or patients:
- ☐ Mental disabilities or cognitive impairments
- ☐ Terminally ill, or illiterate
- ☐ Non-English and non-Arabic speaking
- ☐ Minors
- ☐ Other

c. For research, indicate source of the participants: where you recruit

d. Are there agreements in process with the collaborating sites, or individual consultants? ☐ Yes ☐ No

e. The Consent of participants:
- ☐ Includes only present research
- ☐ Includes future research
- ☐ Includes approval to release data into public database
- ☐ There is action plan in the consent for participants to withdraw consent

f. Where is Genomics research Information stored?
List all locations including cloud options (cloud storage is not permissible for medical care information, but it is for research)

g. Is the documentation of test/research stored in the medical record? ☐ Yes ☐ No

h. Sample identifiers to be used:
☐ A code is assigned
☐ Protected Health Information (PHI) is used as identifier

i) The samples are destroyed after use. ☐ Yes ☐ No
There is language in the agreement with collaborating institutions about sample destruction
☐ Yes ☐ No ☐ Not Applicable

j) Permission is granted in the consent for future tests, including future research use of samples:
☐ At the applicant site
☐ At the 3rd party's site

k) Is there genetic counselling available once results are available?
☐ Yes ☐ No ☐ Not Applicable

l) Is there available psychological support in the case of genetics testing?
☐ Yes ☐ No ☐ Not Applicable

m) For Medical genetic testing analysis, are there external entities involved?
☐ Yes ☐ No ☐ Not Applicable

If yes, list the information they receive

If yes, explain the method of sharing information

n) For Genomics or genetics research are there co-investigators, consultants or mentors residing outside UAE?

☐ Yes ☐ No ☐ Not Applicable

If yes, list the information or samples they receive

If yes, explain the method of sharing information

The co-investigator residing abroad is a solo consultant.

☐ Yes ☐ No ☐ Not Applicable

7. Information Security Compliance and Data Privacy

No	Action	Y	N	N/A	Remarks
1.	**The research involves patient data**	☐	☐	☐	

2.	**Patient data transferred/made available and/or hosted outside UAE at any time during or after the research**	☐	☐	☐	
3.	**Secure data exchange channels defined & agreed for patient data exchange**	☐	☐	☐	
4.	**NDA signed with data recipients as needed/applicable**	☐	☐	☐	
5.	**Data retention period defined & agreed**	☐	☐	☐	
6.	**The research involves parties from outside UAE**	☐	☐	☐	

A. Compliance Requirements

1. Information Exchange
    a. All information exchanged shall be classified, tagged and controlled, as per the requirements of the classification. Please refer ABU DHABI HEALTHCARE INFORMATION AND CYBER SECURITY STANDARD (ADHICS) for more details about Information Classification.
    b. All information exchanged shall be in a pre-defined structure agreed by both parties, which provides the minimum information required for the specific purpose.
    c. All information exchange shall only be through approved channels agreed by both parties, in compliance with requirements of the classification.
2. Administration
    a. All receiving parties shall sign separate NDAs for ensuring maintenance of confidentiality of all information handled.
    b. There shall be binding agreements with parties for ensuring maintenance of confidentiality of all information handled.
3. Further sharing of information
    a. Any, and all requirements to share the information further with any third parties at any circumstances shall be only after obtaining written consent from the Discloser party and DOH.
    b. Any information shared further shall be only after the assurance that the information be classified, tagged and controlled, as per the requirements of the classification.
    c. No third party shall share the information further under any circumstances.
4. Incident Management
    a. Any, and all compromises and breaches shall be informed to the DoH immediately along with the impact analysis and consequences.
    b. Incident report shall be shared with the DoH along with the root cause analysis within 1 day of the resolution of the breach or compromise.
5. Technology & Assurance
    a. The DoH shall be allowed to conduct audits on the premises and systems of the Requestors as deemed without any advanced notice.
6. Termination & Data retention

a. All information shared by the Discloser party shall be deleted immediately from all systems belonging to the Receiver(s) and all third parties upon termination or expiry of the agreement unless mandated otherwise by any applicable laws.
b. The Receiver(s) shall be responsible for protecting the confidentiality of any information thus retained until it is required, post which the information shall be deleted from all systems belonging to the Receiver(s) and all third parties.