INFORMED CONSENT FOR STUDIES INVOLVING GENETIC MATERIAL COLLECTION AND TESTING

Form # KSU-REC 005G-E

King Saud University, Riyadh, Kingdom of Saudi Arabia

INFORMED CONSENT TEMPLATE INSTRUCTIONS TO THE INVESTIGATORS

- Instructions are in *[italics]*.
- _ Indicates that the investigator should fill in the appropriate information. Some places have example text that must be replaced
- Be sure to delete everything that doesn't belong to the present study (including this text box!)!

DELETE THIS BOX PRIOR TO SUBMITTING IT TO THE KSU-IRB

Protocol Number:

Name of Subject:

Medical Record Number:

Study Title:

Principal Investigator:

Sponsor/Non-Commercial Funding/NA:

Address of the PI:

Telephone:

Section A: Research Participant Information Sheet

After receiving full explanation of the intended research project and having all my inquiries about this study answered, I give my consent for voluntary participation in a research project. By signing this document I attest to having full knowledge and understanding of the following:

1. I am participating in this research:
2. Required procedures:
3. Risks involved:
4. Project is Sponsored by/Not applicable:

Section B: Genetic Material/Testing Details

You are asked to participate in a study that requires your genetic material and genetic testing, analysis of DNA/RNA, through your biosamples, collected prospectively for this study by the procedure described to you. This may include routine method of liquid or soft tissue biosamples collection at laboratory or collection of required tissue through surgical excision or resection. This study is subject to general rules in the Kingdom of Saudi Arabia in general and King Saud University in particular. There are certain options the participant has to decide, not conflicting with general rules.

5. **The study requires my genetic testing:**
[Description of genetic testing as part of the study]

6. **What type of genetic test is to be performed?**
[Description of test, name, term and type]

7. **I am informed of the purpose of genetic testing on my biosamples:**
☐ **YES/** ☐ **NO**
[Description of the purpose of genetic test]

8. **I consent for the analysis of my RNA/DNA, through my biosamples.**
☐ **YES/** ☐ **NO**

9. **I have options of getting my genetic test result <u>if/when</u> the study allows.**
☐ **YES/** ☐ **NO**
[Description of genetic test result handing over the subjects with the timeline, if applicable.]

10. **I allow and nominate the person to get my genetic test result on my behalf.**
☐ **YES/** ☐ **NO**

If yes, provide:
Name: Relationship: Signature of nominee:

11. **I am informed that my identifiers will be removed from the genetic material/biosamples.**

☐ **YES/** ☐ **NO**

[Please mention the identifiers subject have in the source document/medical record to be coded or removed. No national or government identity/database information could be allowed with the subject's data]

12. **I am informed that my biosamples/genetic material will be used only for the study I am consenting for.**

☐ **YES/** ☐ **NO**

13. **My biosamples will be destroyed after they are tested within the timeline as specified.**

☐ **YES/** ☐ **NO**

[Description of the timeline, when the subject's biosamples will be destroyed]

14. **I Consent that my biosamples could be stored and used for other (secondary) study/by other investigator, as mentioned in the study procedures described to me, and I do not need to re-consent for another study.**

☐ **YES/** ☐ **NO**

15. **I am informed that unknown or inherited disease could be detected from the genetic testing.**

☐ **YES/** ☐ **NO**

16. **I am informed that my genetic material/biosamples will be sent outside the Kingdom of Saudi Arabia (KSA) for genetic testing, and my identifiers will coded or removed.**

☐ **YES/** ☐ **NO**

17. **I am informed that if a Treatable inherited disease is found I my test, I will be guided for the confidential treatment in or outside KSA.**

☐ **YES/** ☐ **NO**

18. **I am informed about 'what clinical data' is required for my genetic testing.**

☐ **YES/** ☐ **NO**

[Please mention subjects clinical data required for the genetic testing, to ensure the limitations of privacy and confidentiality]

Section C: Research Subject Consent

The research and procedures have been explained to me. I have been allowed to ask any questions I have at this time. I can ask any additional questions I may think of later. I may refuse to participate in the study, and I may quit being in the study at any time without any penalty and without affecting my health care.

I will receive a signed copy of this consent form.

I agree to participate in this study. My agreement is voluntary. I do not have to sign this form if I do not want to be part of this research study.

Subject Name: _____

Subject Signature: _____

Date: ___ / ___ /_____ (H); ___ / ___ /_____ (G)

Time: (AM ☐ _____ PM ☐_____)

Person Obtaining Consent (Designated by PI):

I have explained the nature and purpose of the study and the risks involved. I have answered and will answer questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Name: _____

Signature: _____

Date: ___ / ___ /_____ (H); ___ / ___ /_____ (G)

Time: (AM ☐_____ PM ☐_____)

Principal Investigator: _____

Signature of Principal Investigator:

Date: ___ / ___ /_____ (H); ___ / ___ /_____ (G)

Time: (AM ☐_____ PM ☐_____)

Section D: Do not use the following signature lines unless third party consent is being requested (for subjects who are unable to give consent.

For subjects unable to consent

Legally Authorized Representative:_____

Date: ___ / ___ /_____ (H); ___ / ___ /_____ (G)

Person Obtaining Consent:_____

Date: ___ / ___ /_____ (H); ___ / ___ /_____ (G)

For children who cannot give consent

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

Parent or Legal Guardian: _____

Date: ___ / ___ /_____ (H); ___ / ___ /_____ (G)

IMPARTIAL WITNESS: In above case(s), when subject is unable to read and/or understand the text and nature of the ICF and the study, a witness is required.

Witness name:_____

Relation, if any, with subject: _____

Signature:

Date: ___ / ___ /_____ (H); ___ / ___ /_____ (G)

Person Obtaining Consent:----------

Date: ___ / ___ /_____ (H); ___ / ___ /_____ (G)

Principal Investigator:

Signature of Principal Investigator:

Time (AM ☐_____PM ☐_____)

*For more information, please visit the website of Research Ethics Committee in King Saud University (*http://dsrs.ksu.edu.sa/ar/comm_Policies*)*