JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)

UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG,

SELANGOR, MALAYSIA



FORM 2.7: INFORMED CONSENT FORM (TEMPLATE) – GENOMIC - ENGLISH

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

FOR WHOLE- GENOME/GENETIC RELATED STUDIES

(WHOLE GENOME/GENETIC RESEARCH PROJECT)

1. ***Research Subject Infomation and Consent Form*** *used in the Genetic/Whole-Genome related Research Project must be according to the following information formats:*
* *Topic of the Research*
* *Introduction*
* *Purpose of the Study*
* *Study Procedures*
* *Risks*
* *Possible Benefits*
* *Incidental Findings*
* *Disclosure of Research Results*
* *Questions*
* *Confidentiality*
* *Withdrawal from the study*
* *Signatures*
1. *As an* ***EXAMPLE****, please refer to the attached Research Subject Infomation and Consent Form.*
2. **ATTACHMENT D – Research Information**
3. **ATTACHMENT E – Research Subject Information and Consent Form**
4. **Information for researchers:** This template serves only as an example for you to build your own Informed Consent form that suits the need and specificity of your research. However, all components of Informed Consent as specified in (A) above must be present. Texts highlighted in red inthis templateshould be replacedwithspecific informationrelated to your studies, orserveas an explanation to you. Before submitting to the JKEUPM Secretariat, please make sureallthe texts in redare no longer thereandreplacedwithspecific information of your research.

EXAMPLE ATTACHMENT D

RESEARCH INFORMATION

*Research Title* : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Researcher’s Name* : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

#### 1.0 INTRODUCTION

You are invited to take part voluntarily in a research study of *[specify the study]*. Before agreeing to participate in this research study, it is important that you read and understand this form. If you participate, you will receive a copy of this form to keep for your records.

DNA, or deoxyribonucleic acid, is the hereditary material in humans and almost all other organisms. Nearly every cell in a person’s body has the same DNA.DNA of a person is a combination of roughly half the DNA of the father and half DNA of the mother. People from the same family or ethnicity may share similar DNA variations. Science behind DNA is continuous exploration in order to understand biology of life, both normal and abnormal.

2.0 PURPOSE OF THE STUDY *[whole genome, exome sequencing or other whole genomics-related analysis research]*

We are requesting your permission to perform whole *[specify type of analysis, i.e. genome and/or exome sequencing]* on your *[specify type of specimen, i.e. blood and/or tissue samples]* and link this to your medical and/or family history.

Your sample(s)*[specify any correlations, i.e. medical and family history information]* will help us study how genes *[specify purpose of analysis]*. (Specify how the findings of the study will be utilised and disseminated.)

3.0 STUDY PROCEDURES

As much as *[specify how much of sample will be taken]* of your *[specify the type of tissue/specimen ie. blood]* will be withdrawn by a qualified officer. The *[specimen]* will then be processed to obtain *[specify the type of molecular substance extracted ie. DNA, mRNA, total RNA, etc.]*. This will be processed using *[specify methodology]* to identify *[specify what will be identified, eg. mutation of a gene – be as specific or as broad as researchers intend to explain, what is the nature of likely future use of the sample]*.

* + - Explain if Research Subject is required to visit the specific institution, how many times and for what purpose in each visit, as well as duration of the involvement of the subjects in the study
		- Explain if other medical examination will be carried out. If another time or venue is involved, please state.
		- Explain if analysis on medical record will be carried out. State type of medical records involved.

4.0 RISKS

 4.1 Physical Risks *[as appropriate]*

 Obtaining blood can ocassionally cause pain, bleeding, bruising, or swelling at the site of the needle stick.Fainting sometimes occurs and infection rarely occurs.

 4.2 Psychological or Social Risks Associated with Possible Loss of Privacy

Your privacy is very important to us and we will use many safety measures to protect your privacy. *[specify the safety measures taken]*. Neither the public nor the controlled-access databases developed for this project will contain information to identify you, such as your name, address, telephone number, or identity card number.

However, in spite of all of the safety measures, it is not possible to absolutely seal your identity from being revealed.Below are some situations that illustrate some risks:

1. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.

2. People may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative).

3. It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

4. Since some genetic variations can help to predict the future health problems of you and your family and relatives, this information might be of interest to health providers, life insurance companies, and others.

5. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. (What are the obligations of the researcher with regard to this? For eg Will respondents be informed before the information is shared with agencies etc. Are there any specific acts/laws that are being referred to that compels researcher to reveal such information? How will the information about genetic be used? Pls specify.)

6. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease.

7. Malaysian DNA Act 2009 stated that in the case of crime investigation, the police reserve the authority to collect DNA information of crime suspects. In such case where you are suspected of a crime, become subject of police crime investigation and the police request to collect your DNA information, the researchers are obliged to do so.

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Signature of Research Subject or Legal Representative

#### 5.0 POSSIBLE BENEFITS [Benefit to Individual, Community, University]

*(Researchers are required to choose one or specify in case both are applicable)*

 5.1 Are there any benefits to participating in the project? No Benefit

You will not benefit personally from giving a sample for this project because this kind of research usually takes a long time to produce medically useful results. However, your participation will increase our understanding about *[specify the knowledge or other scientific benefit gained from this study]*. We think the information gained during this study may contribute to the medical care, treatment and prevention of problems for others in the future.

5.2 Are there any benefits to participating in the project? Benefit

Possible benefits to you could include: [include as applicable]

* A specific change in your genes is the reason for your personal history of [specify the disease under study].
* Information about the risks for [specify the disease under study] to your children which may help manage their healthcare.
* New and better treatments may be an option depending on the genetic result(s).

This study may increase our understanding about *[specify the knowledge or other scientific benefit gained from this study]*. We think the information gained during this study may contribute to the medical care, treatment and prevention of problems for others in the future.

6.0 INCIDENTAL FINDINGS

Gene changes may be identified but they are not related to this study. These are known as “incidental medical findings”. These include:

* Changes in genes that are related to diseases other than that studied in the current research.
* Changes in genes that are not known to cause any disease. These are known as normal variations.
* Changes in genes that are new and of uncertain clinical importance. This means that we do not

know if they could cause or contribute to a disease or if they are normal variations

**6.1 Where knowledge is available presently**

It is possible that we will find gene changes or genetic variants that are unrelated to this study. If we find a change in a gene that is important to you or your family’s health, please let us know your preference by initialing one of the following statements:

\_[ ]\_\_\_ I DO NOT want to be contacted if genetic variants with potential health implications (PHIs)\* are discovered.

\_[ ]\_\_\_I DO want to be contacted if genetic variants with PHIs\* are discovered. (You will be given a choice to learn or not learn about a genetic change that we find.)

If you choose the first option, we will not inform you of the incidental finding and will not commence on further clinical confirmation of the results.

If you choose the second option, the results will need to be confirmed in a clinical laboratory. *[specify how long you will look for other relevant genetic changes, i.e. one time only, for a period of time]* If you want this to be done, we need to draw an additional blood sample and send it for confirmatory testing. Once the results are available, and you would like to review your results, we will invite you to come to ourinstitution to have genetic education and counseling to explain this result.

**6.2 Where knowledge is not available presently but may become available in the future**

If we find gene changes that are not known to be important at this time, we will not share that information with you. However, as this is a rapidly changing field, it is possible that genetic variants that are not known to be important at this time may be shown to be important at a later date. If you are receiving care from another physician who thinks that this testing may be of use in your care and treatment, you may contact us at any time and we will share the results with your physician.

Please let us know your preference by initialing one of the following statements:

\_[ ]\_\_\_ I DO NOT want to be recontacted if genetic variants with Potential Health Implications (PHIs) are discovered.

\_[ ]\_\_\_I DO want to be recontacted if genetic variants with Potential Health Implications (PHIs) are discovered. (You will be given a choice to learn or not learn about a genetic change that we find.)

6.3 Significant non health-related Incidental findings

 *(This part is optional, only when applicable)*

If we find incidental findings which are not related to your health but may be of significant importance to you or your family(eg. incidental finding of non-paternity), please let us know your preference by initialing one of the following statements:

\_[ ]\_\_\_ I DO NOT want to be contacted if genetic variants of such nature are discovered.

\_[ ]\_\_\_I DO want to be contacted if genetic variants of such nature are discovered. (You will be given a choice to learn or not learn about a genetic change that we find.)

7.0 DISCLOSURE OF RESEARCH RESULTS

*(Researchers are required to choose one or specify in case both are applicable)*

7.1 Research Results-non disclosure

We will not give you any individual results from your whole [genome and/or exome] sequencing. This is because it will probably take a long time for this project to produce health-related information that we will know how to interpret accurately. However, we will tell you if we find that you have a condition, such as communicable disease that we are required by law to report. *[Specify whether and how you will summarize research results for participants.]*

In the event of non-communicable diseases, specify how the interests of research subjects are safeguarded.

7.2 Research Results-disclosure

When we have useful results from the genome sequencing we have done, we will contact you and ask you if you want to learn the results. We will ask you to come back to the institution to learn the results in *[specify the time required from specimen collection to return of result to the participant, if possible]*. You will meet with professionals with the expertise to help you learn more about the risks, benefits and limitations of learning your research results. If you then decide to receive your results, the research team will explain the meaning of these results and any implications for your and/or your family’s health.

#### 8.0 CONTACT PERSON/QUESTIONS

Please contact the Principal Investigator, *[name of Principal Investigator]* at phone number *[give cellphone number]* and/or email *[give email address]* for all research-related matters and in the event of research-related injuries.  If you feel uncomfortable contacting the Principal Investigator, you could also contact the *[give name of collaborator/other team researcher]* (collaborator/research team contact) at phone number *[give cellphone number]*     and/or email *[give email address]*.

For an independent opinion regarding the research and the rights of research participants, you may contact a staff at the UPM Research Ethics Committee

Secretariat of Ethics Committee for Research Involving Human Subjects

Office of The Deputy Vice Chancellor (Research and Innovation),

Universiti Putra Malaysia

Tel. No. : 03-89472502/89471244

Email : normala\_ib@upm.edu.my

#### 9.0 CONFIDENTIALITY

Your medical information will be kept confidential and will not be made publicly available unless disclosure is required by law.

Your samples will be anonymous(non-identifiable) (i.e. personal identifiers will not be kept with your sample and the sample will not have a code number that can be used to identify you) or coded and considered de-identified (i.e. any identifying information such as name will be replaced with a code and only a few authorized people will have access to this code to link samples and data back to personal identifiers).

*(Optional, in case of reportable conditions, such as HIV status)*

*As per government regulation [specify the regulation, if any], we are required to report your condition [specify the condition] to the Ministry of Health [specify the MOH office concerned].*

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original medical records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying clinical trial procedures and/or data. Your medical information may be held and processed on a computer.

By signing this consent form, you authorize the record review, information storage and data transfer described above.

9.1 PUBLIC DATA RELEASE

*(This part is optional depending on whether researcher intend to submit the data to a shared database)*

Data obtained from this study, which does not directly identify you personally, may be submitted to a [nationally/internationally] shared database [specify the name of the database and if it is a paid or free access] and published in scientific journal. Data that has been submitted to a database or published in scientific journal can not be retracted if you withdraw from the study and request that all your data be eliminated and remaining biological samples be destroyed. In this regard, it is has to be understood that submission into database and publication in scientific journals limit the efforts of withdrawal.

Please let us know your preference by initialing one of the following statements:

\_[ ]\_\_\_ I DO NOT want the data generated from my biological specimens to be submitted into the database

\_[ ]\_\_\_I DO want the data generated from my biological specimens to be submitted into the database

9.2 SAMPLE/DATA STORAGE AND WITHDRAWAL FROM STUDY

Any blood or tissue specimens obtained during the course of this study will be stored and analyzed only for the purposes of this study for a period not exceeding *[specify time length]* years, and will be destroyed after completion of the study. However, if you agree to allow us to keep the tissues or blood samples for future studies after this project is completed, please let us know your preference by initialing one of the following statements:

\_[ ]\_\_\_\_ I agree to allow my tissues or blood samples to kept for future studies after this project is completed

\_[ ]\_\_\_\_I do not agree toallow my tissues or blood samples to kept for future studies after this project is completed

Your biological sample will be destroyed and your data will be eliminated when you express withdrawal from the study. However, the samples and data generated from your samples that have already been distributed to other research centers or placed in the research databases or published in scientific journals or other form of publications cannot be withdrawn.

If you would like to withdraw from this project you can contact *[Insert Name & Contact Information of Principal Investigator]* at *[Insert Name of Institution]* and he/she will destroy any remaining samples and written information of yours that have been obtained for the study.

 ATTACHMENT E

Research Subject Information and Consent Form

I …………………………………… Identity Card No. …………………………… address………………………………………………………………………………………………………... ……………………………………………………..hereby voluntarily agree to take part in the research stated above \*(clinical /drug trial/video recording/ focus group/interview-based/ questionnaire-based).

I have been informed about the nature of the research in terms of methodology, possible adverse

effects and complications (as written in the Respondent’s Information Sheet). I understand that I have the right to withdraw from this research at any time without giving any reason whatsoever. I also understand that this study is confidential and all information provided with regard to my identity will remain private and confidential.

\* delete where necessary

Signature ……..………………………… Signature ……..………………………….

 (Respondent) (Witness)

Date :………………………………….….. Name :………………………………….…..

 I/C No. :………………………………….…..

I confirm that I have explained to the respondent the nature and purpose of the above-mentioned research.

Date ……..………………………… Signature ……..………………………….

 (Researcher)