

مستشفى الملك فيصل التخصصي ومركز الأبحاث

KING FAISAL SPECIALIST HOSPITAL AND
RESEARCH CENTRE

INFORMED WRITTEN CONSENT

موافقة متنورة

Part I: RESEARCH PARTICIPANT INFORMATION SHEET

الجزء الأول: معلومات عن الدراسة للمتطوع في البحث

أنا.....

After receiving full explanation of the intended research project from **Dr. Riad El Fakih** or any authorized individual and having all my inquiries about this study answered I, the undersigned, give my consent that I am participating in a research project.

THE PROJECT I AM ASKED TO PARTICIPATE IN IS ENTITLED:

The purpose of this research is to

My participation requires that:

1)

The risks and discomfort involved in participation are:

Potential benefits:

My participation is completely voluntary and my decision will not affect the medical care we receive. I can refuse participating without prejudice from my treating physician.

If I do not enroll in this study the available alternative is:

Not to perform the genetic analysis. I will then continue to receive the required clinical care.

I can withdraw from this study whenever I wish, and I can request disposing of any information or samples taken from me without affecting the medical care I am entitled to receive.

I will bear no extra cost as a result of my participation in this study. In case of any injury resulting from my participation, the King Faisal Specialist Hospital and Research Center will provide me with the necessary medical care.

I understand that the information generated from my participation in this project will be **kept confidential** and no person or entity will have access to it besides those directly involved in the study. There will be no reference to my identity or my tribe in any published article

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about this study. I will be (not) informed about my results from this study. My treating physician will be (not) informed about my results from this study.

Contact persons:

I may call the Section of Assurance & Compliance, Office of Research Affairs telephone 4647272, ext. 32934 for general questions concerning research at KFSHRC or research subjects' rights. For specific questions on this study, or in the event of research-related adverse events, I may call Dr xxxx telephone 4647272, pager: xxxxx.

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KING FAISAL SPECIALIST HOSPITAL AND
RESEARCH CENTREPART II: CONSENT FOR STUDIES INVOLVING
GENETIC MATERIAL (DNA/RNA)

I am asked to participate in a study that involves analysis of DNA/RNA (the genetic material in the cell), this type of study is subject to the rules of the Kingdom of Saudi Arabia in general and King Faisal Specialist Hospital and Research Centre in particular. There are certain options that I can choose from.

I have studied the following options carefully and checked the statements that I do accept.

1. I want / I Don't want :
To receive a general summary of the study results.
2. I want / I Don't want :
To receive the results of the study that belong to me (and/or my family).
3. I want / I Don't want :
To be asked to give consent before my (and/or my family's) leftover samples are used in other studies.
4. I want / I Don't want :
To be asked to give consent before my (and/or my family's) leftover samples are used in studies related to this study.
5. I want / I Don't want :
To remove all identifying information that links the sample to my (and/or my family's) identity once this study is completed.
6. I want / I Don't want :
My (and/or my family's) leftover samples to be destroyed once this study is completed.

I have carefully studied the above-mentioned options and checked what I do agree with and I sign this consent with full understanding.

Research Subject or Surrogate:

Print Name _____

Signature: _____ Date: _____

Relationship: _____
(if signed by person other than the research subject)

الجزء الثاني : الموافقة المتتورة على دراسة على المادة الوراثية

الْبَحْث الَّذِي طُلِبَ مِنِّي الْمَشَارَكَة فِيهِ يَتَضَمَّنُ تَحْلِيلًا لِلْجِينَاتِ وَهِيَ الْمَوَادُّ الْوَرَاثِيَّةُ فِي الْخَلَايَا. هَذَا النَّوْعُ مِنَ الدِّرَاسَةِ يَخْضَعُ لِلنُّظْمِ الْمَرْعِيَّةِ فِي الْمَمْلَكَةِ الْعَرَبِيَّةِ السُّعُودِيَّةِ بِصِفَةِ عَامِهِ وَفِي مَسْتَشْفَى الْمَلِكِ فَيْصَلِ التَّخْصِصِيِّ وَمَرْكَزِ الْأَبْحَاثِ بِصِفَةِ خَاصَّةٍ. هُنَاكَ خِيَارَاتٌ مُعَيَّنَةٌ يُمْكِنُ لِلْمَشَارِكِ أَنْ يَخْتَارَ مِنْهَا.

إِنِّي قَدْ دَرَسْتُ الْخِيَارَاتِ التَّالِيَةَ بِعِنَايَةٍ وَاخْتَرْتُ مِنْهَا مَا أُوَافِقُ عَلَيْهِ.

1. أريد / لا أريد :
أن أُعْطَى مُلْخَصًا عَنِ نَتَائِجِ الدِّرَاسَةِ بِشَكْلِ عَامٍ.
2. أريد / لا أريد :
أن أُعْطَى النَتَائِجِ الْخَاصَّةِ بِي (و/ أَوْ بِأَسْرَتِي) الْمَتَّعَلِقَةِ بِهَذِهِ الدِّرَاسَةِ.
3. أريد / لا أريد :
أَنْ تُؤَخَّذَ مَوَافَقَتِي قَبْلَ اسْتِخْدَامِ الْمَتَّبَقِيِّ مِنْ عَيْنَاتِي (و/ أَوْ عَيْنَاتِ أُسْرَتِي) فِي دِرَاسَاتٍ أُخْرَى.
4. أريد / لا أريد :
أَنْ تُؤَخَّذَ مَوَافَقَتِي قَبْلَ اسْتِخْدَامِ الْمَتَّبَقِيِّ مِنْ عَيْنَاتِي (و/ أَوْ عَيْنَاتِ أُسْرَتِي) فِي أَبْحَاثٍ ذَاتِ صِلَةٍ مِثْلَ هَذَا الْبَحْثِ.
5. أريد / لا أريد :
أَنْ يُزَالِ كُلُّ مُؤَشِّرٍ يَرْبِطُ الْعَيْنَاتِ بِشَخْصِي (و/ أَوْ بِأَسْرَتِي) عِنْدَ اسْتِكْمَالِ هَذَا الْبَحْثِ.
6. أريد / لا أريد :
إِتْلَافِ الْمَتَّبَقِيِّ مِنْ عَيْنَاتِي (و/ أَوْ عَيْنَاتِ أُسْرَتِي) عِنْدَ اسْتِكْمَالِ هَذَا الْبَحْثِ.

لَقَدْ دَرَسْتُ الْخِيَارَاتِ الْمَذْكُورَةَ أَعْلَاهُ بِتَمَعْنٍ وَاخْتَرْتُ مِنْهَا مَا رَأَيْتُهُ مَنَاسِبًا وَعَلَى هَذَا أَوْعٍ.

المشارك بالبحث أو ولي الأمر:

الاسم: _____

التوقيع: _____ التاريخ: _____

صلة القرابة _____

(إذا كان الموقع غير المريض المشارك)

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WITNESS

I confirm that I have accurately translated and/ or read the information to the subject:

Print name: _____

KFSH&RC ID#: _____

Signature: _____ Date: _____

الشاهد

أقر بأنني قد قرأت / أو ترجمت للمشارك هذه المعلومات بشكل صحيح.

الاسم: _____

رقم بطاقة المستشفى: _____

التوقيع: _____ التاريخ: _____

Investigator or Delegate

I have fully explained to the above volunteer/ relative/ surrogate the nature and purpose of the above-mentioned research project.

Print Name: _____

KFSH&RC ID#: _____

Signature: _____ Date: _____

الباحث أو ممثله

أقر بأنني قد شرحت للمتطوع/ لقربيه/ أو ولي أمره المذكور أعلاه بصورة كاملة طبيعة وأهداف الدراسة المذكورة.

الاسم: _____

رقم بطاقة المستشفى: _____

التوقيع: _____ التاريخ: _____