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| IRB-400 Informed Consent Form For Research Study | |
| Protocol Title: | Enter Protocol Title |
| Protocol Number: | Enter Protocol Number |
| Sponsor: | Enter Sponsor |
| Principal Investigator: | Enter Principal Investigator Full Name |
| Site Address: | Enter Site Address |
| Telephone Number: | Enter Telephone Number |
| 1. **Introduction** | |
| Before agreeing to participate in this research study, please read and understand the following explanation of the proposed study. This informed consent form describes the purpose, procedures and risks of the research study. It also describes your right to withdraw from the research study at any time, and that you are volunteering. Also, that no guarantees or assurances can be made as to the results of the study. Please feel free to ask questions. | |
| 1. **Background and Purpose** | |
| The background and purpose of this research study is to [describe]  Explain the background of the research problem. For example, explain to the subject the current therapies for their disease and why they are not satisfactory. For non-therapeutic studies, explain the scientific problem. Describe how this research will attempt to solve the problem.  We invite you to take part in this research study because [describe the condition or the circumstances that make the subject eligible to participate in this research study.]  for example because you have thalassemia or because you are taking insulin or because you are healthy and we are recruiting controls. | |
| 1. **Number of Subjects** | |
| About [number] subjects will participate in this site out of [number] subjects in the entire research study [choose an item.] | |
| 1. **Research Study Duration and Length of Participation** | |
| Your participation in this research study will last approximately [number] of weeks/months/years and will include [number]visits to the research study center. We also expect that this research study will last approximately [number] of weeks/months/years. | |
| 1. **Procedures** | |
| Your participation will involve….  [Use easily understandable terms to give a detailed description of what participants will be asked to do, e.g. you will participate in three separate surveys which will each take 15 minutes. If blood is to be drawn, indicate the amount [in units, teaspoon] and frequency. Indicate all hospitalizations, outpatient visits and telephone or written follow-up; the length and duration of visits and procedure.  State where and when this research will be done and with whom will the subject interact.]  If you agree to participate, the researchers will also collect…  [Discuss any data about the participant that you will gather that you are not receiving directly from them, as well as the source (e.g. medical history from hospital or clinic records).  For studies that also include involvement of routine clinical care, differentiate procedures being conducted solely for research. List what is being performed as part of the research study and what is being performed as part of standard care. List what procedures are part of regular medical care that will be done even if the subject does not take part in the research.  If your procedures are experimental list these procedures and therapies and identify them as such, and indicate how often procedures will be performed.  Provide a description of the randomization procedures, if applicable, and describe the chances of being assigned to any one group. Define randomization in simple language such as “by chance, or flipping a coin”  Describe any responsibilities of the subject.]  *Add the following if applicable:*  *We may use the genetic material (genes, DNA, RNA) in your sample to learn about the role genes play in health and disease to promote a better understanding or prevention of health conditions and/or disease. Genetic studies help explain why traits or diseases are passed down in families. Results of genetic studies may also reveal information about your family members.*  *The genetic testing may include whole genome sequencing. This means a researcher would map your entire set of genetic instructions. Genetic instructions are what make you unique. These tests involve scanning the genomes from many different people and looking for markers that scientists can use to predict the presence of a disease. Data obtained from analyzing your genomic information and your medical information may be put into scientific databases along with information from other research participants. We will remove your name and other information that could be used to identify you before placing the genomic data in public databases.*  *Researchers may use your sample to create a “cell line” which is cells grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.* | |
| 1. **Alternative Procedures** | |
| Rather than participate in this research, you might prefer alternative procedures such as:   * List appropriate alternatives.   For clinical trials describe the important risks and potential benefits of the alternative procedures and courses of treatment.  *Or delete above and replace with:*  This study is for research purposes only. The only alternative is to not participate in this research study. | |
| 1. **Risks, Side Effects and/or Discomforts** | |
| If there are risks to participation, describe them for each procedure. The participant may more easily understand the risks of procedures in the research study if the information is presented in table form, graphic, or visual aid.  For example: Risks and side effects of research study procedures may include:   * *Blood samples: possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.* * *Electrocardiography (ECG): Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used.* * *Questionnaires: You may feel uncomfortable or embarrassed by some of the questions in the questionnaires you will be asked to complete*.   When applicable, group the risks into those that are expected, ranking them as rare, occasional, or often, and describe them as such.  When applicable, in lay terms, list all reasonably expected side effects and those that are life-altering or potentially life-altering, no matter how rare.  If applicable, Explain risks with ramifications. For example, what could happen if the participant experiences tightness in his/her chest during physical exercise being done for the research study, what will happen to the subject if liver enzyme tests indicate an abnormality or what are the consequences of a breach of confidentiality relative to sensitivity of personal information?  *Add the following if applicable:*  *Significant risk of social harm (for example, social exclusion or discrimination), psychological & emotional harm, (for example, embarrassment, fear or guilt) , privacy harm (for example, accidental disclosure of your personally identifiable medical information) or financial harm (for example, having to pay money out-of-pocket for research or medical expenses, losing health insurance, or being unable to obtain a job).*  *Even without your name or identifiers, genetic information is unique to you making it possible for someone to trace it back to you. The results of genetic research apply to both you and your family members. Genetic information used improperly to discriminate or support negative stereotypes could cause you or your family distress*  *There may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to you that we cannot foresee now.* | |
| 1. **Unforeseen Risks** | |
| There may be other risks of research study participation that are unknown. | |
| 1. **Pregnancy** *(include if applicable)* | |
| Participation in this research study may involve unknown risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant or are breastfeeding a child, you cannot participate in this research study. | |
| 1. **New Findings** | |
| Any new important information that is discovered during the research study and which may influence your willingness to continue participation in the research study will be made available to you. This might include changes in procedures, changes in the risks or benefits of participation, or any new alternatives to participation that the researchers learn about. | |
| 1. **Individual Results from the Research Tests/Surveys** | |
| Generally, tests/surveys done for research purposes are not meant to provide results or clinical information that apply to you alone.  *Or delete above and replace with:*  You may be given feedback about the results or clinical information from your tests or surveys done for purposes of this research. | |
| 1. **Benefits** | |
| This study is for research purposes only. There is no direct benefit to you from your participation in the research study. Information learned from the research study may help other people in the future.  Or delete above and replace with:  We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include describe  First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. For example, an investigational drug provided for free may not be available at the end of the research or may no longer be provided free if the drug becomes available for marketing.  Note that payment to subjects is not considered a benefit; payment details should be described in the “compensation for participation” section below. | |
| 1. **Costs** | |
| Taking part in this research study may lead to added costs to you (Describe what these costs are. Indicate what will be charged to insurance and what will be paid for by the research study).  Or delete above and replace with:  There will be no charge to you for your participation in this research study. The research study-related procedures and study visits will be provided at no charge to you or your insurance company. | |
| 1. Compensation for Participation | |
| For your time and effort related to your participation in this research study, you will be paid up to a total of [Currency Amt] if you complete this research study. If you do not complete the research study, for any reason, you will be paid for the research study visits you do complete according to the following schedule:  [Currency Amt] for [visit number]  [Currency Amt] for [visit number]  [Currency Amt] for [visit number]  Or delete above and replace with:  You will not receive any monetary compensation for your participation in this research study. | |
| 1. **Research Related Injuries** | |
| If you are injured or made sick from taking part in this research study, call Principal Investigator or name the research staff immediately, T. +974-XXXX-XXXX, or alternatively contact Sidra Medicine Emergency Department.  Medical care will be provided to you at Sidra Medicine at no charge.  In case we were unable to provide care to you at Sidra, we will arrange and pay for your care at Hamad Medial Corporation (HMC). If you receive care at another institution, you or your insurance will have to pay for that care in accordance with the policies of that institution.  Sidra Medicine has no program or funds set aside to compensate you for research-related injuries or to pay for medical care for research-related injuries at institutions other than HMC or Sidra.  Contact the Principal Investigator for more information. | |
| 1. **Confidentiality** | |
| Records of your participation in this research study will be held confidential except as disclosure is required by law or as described in this informed consent document. Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information.  The investigator, authorized research personnel, the sponsor or its authorized personnel, auditors, MOPH, other regulatory agencies (when applicable) and the Institutional Review Board (IRB) will be able to inspect and copy confidential research study-related records which identify you by name. They will be granted direct access to your medical records for verification of the research procedures and date. Therefore, absolute confidentiality cannot be guaranteed. By signing this document, you are authorizing this access.  We may publish the results of this research. However, we will keep your name and other personal identifying information confidential.  *Add the following if applicable:*  *We will take careful steps to keep your information confidential*, (Insert description of procedure(s) used for protecting confidentiality of data including paper records, computer records, jump drives and portable storage devices).  *We will store samples in* (specify, e.g. a locked freezer that is located behind locked doors). We will store your identifiable information, in a (specify, password-protected database; encrypted file which changes it to another format to protect it from being accessed by anyone outside of the approved staff).  *We will remove your name or other direct identifiers from your information or samples. We will label your information or samples with a code. We will store the key that links the code to your identity separately. Only select staff will have access to the list that links the code to you.*  *The staff follow procedures to keep your identity secret to the extent allowed by law. In very unusual cases, staff may be required to release your identifiable medical and research information to the extent allowed by law.*  For FDA regulated clinical trials only, include this statement as is: A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. | |
| 1. **Commercial Gain** *(include if applicable)* | |
| Your information or samples collected during this research study will no longer belong to you. Information or samples may be used for the development of new products, treatments, processes or services for commercial sale.  There are no plans to offer you financial compensation or share any profits with you or your relatives should this occur.  You will not, however, lose any legal rights to which you are entitled by signing this consent. | |
| 1. Research Team Contact | |
| During the research study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the research study, contact the investigator, [name, T. +974-XXXX-XXXX] | |
| 1. **IRB Contact** | |
| An Institutional Review Board (IRB) is an independent committee established to help protect the rights of research subjects. IRB at Sidra has reviewed and approved this research study. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, Email: [irb@sidra.org](mailto:irb@sidra.org), or T. +974-4003-7747 during business hours Sunday- Thursday 7:30 a.m. to 4:00 p.m. | |
| 1. **Voluntary Participation/Withdrawal** | |
| Your decision to participate in this research study is voluntary. You may choose to not participate or you may withdraw from the research study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.  If there are adverse consequences to withdrawing from the research, add the following:  If you decide to leave the research study, describe the adverse consequences, e.g. subjects on a drug may experience worsening of their disease or withdrawal problems without substituting another drug or tapering the research study drug. If you decide to leave the research, contact the investigator so that the investigator can describe the procedures for orderly termination/withdrawal by the subject).  The investigator or the sponsor can stop your participation at any time without your consent for the following reasons:   * If you fail to follow directions for participating in the research study; * If it is discovered that you do not meet the research study requirements; * If the research study is cancelled. | |
| 1. **Storing and Sharing Your Information or Samples for Future Use** *(include if applicable)* | |
| We would like to store, use, and share (specify what will be stored for future use, e.g., your leftover specimens, extra tissue samples, blood samples, other biologic samples, health information, etc.), for future research. Having information or samples from many people helps researchers identify trends and discover better ways to diagnose, prevent, and treat many conditions. Researchers can use the stored information or samples to learn more about cancer, diabetes, and other health problems or research additional scientific questions. | |
| 1. Place and Duration of Storage of Information or Samples (include if applicable) | |
| The information will be stored at (describe location/facility) for (indefinitely, for no longer than XXX years/months).  Explain who will have access to the Information or specimens. | |
| 1. Withdrawal of Your Information or Samples from Future Use (include if applicable) | |
| You may withdraw your permission to allow your information or samples to be used for future research. To do so, you must inform the PI or research team about your decision either verbally or by sending a written withdraw request to (insert address).  We will destroy any remaining information and samples that have been stored. In addition, it may be possible to destroy the code that links you with your information and specimen samples. However, we cannot withdraw the information and samples that have already been used. | |
| 1. Providing Information or Samples to other Researchers (include if applicable) | |
| Sidra Medicine may collaborate with other researchers, requesting access to information or samples must (specify, complete an application process; sign an agreement). Such, researchers who receive your information or sample will sign an agreement to use the data responsibly.  Before sharing your information or samples, we will remove identifiers such as (e.g., your name, medical record number, or date of birth).Your de-identified information or samples may be shared with other Sidra researchers and researchers outside of Sidra, without your additional informed consent.  Or delete above and replace with:  Before sharing your information or samples, we will replace identifiers such as (e.g., your name, medical record number, or date of birth) with a code.Your coded information or samples may be shared with other Sidra researchers and researchers outside of Sidra, without your additional informed consent. | |
| 1. Optional Future Use: | |
| Do you give permission for investigator name under the auspices of Sidra Medicine to store and share your (specify information and/or samples) for future research in compliance with applicable regulations and institutional policies?   **Yes**  **No** Subject Initials  Remember, you can still be in the main research study even if you even if you do not wish to allow your information and/or specimens stored for this investigator’s future research. | |
| 1. **Participating in Future Studies** *(include if applicable)* | |
| The research staff would like to contact you with information about participating in future studies.  You give your permission for the investigator or staff to contact you regarding your willingness to participate in future research studies?  **Yes**  **No** Subject Initials | |
| 1. Consent | |
| I have read and understand the information in this informed consent document. I have had an opportunity to ask questions. All my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document. | |
| Subject | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed Name of Subject  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_  Signature of Subject Date (dd/mm/yyyy) Timing (hh:mm) | |
| Person Obtaining Consent | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed Name of the Person Obtaining the Consent  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_  Signature of the Person Obtaining the Consent Date (dd/mm/yyyy) Timing (hh:mm) | |
| Impartial Witness/Interpreter (In case of translation) | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed Name of Impartial Witness/Interpreter  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_  Signature of Impartial Witness/Interpreter Date (dd/mm/yyyy) Timing (hh:mm) | |
| Consent for Subjects Who Cannot Read *(include if applicable)* | |
| The research study subject has indicated that he/she is unable to read.  The consent document has been read to the subject by a member of the research study staff, discussed with the subject by a member of the research study staff, and the subject has been given an opportunity to ask questions of the research study staff.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed Name of Impartial Witness/Interpreter  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_  Signature of Impartial Witness/Interpreter Date (dd/mm/yyyy) Timing (hh:mm)  *\*Impartial Witness: A person, who is independent of the research study, who cannot be unfairly influenced by people involved with the research study, who attends the informed consent process if the subject or the subject’s legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance*  *\*Interpreter: is an Impartial Witness who is invited to read and translate the informed consent form and signs as a witness when the subject and person obtaining consent cannot read and speak the same language (example: English speaking person obtaining consent from an Arabic speaking subject). The Interpreter must be fluent in the language of the person obtaining consent and the subject’s language* | |
| 1. **For Children Who Become Adults** *(include if applicable)* | |
| My parents/legally authorized representative agreed for me to participate in this research study as a minor. I have read and understand the information in this informed consent document.  I have had an opportunity to ask questions. All my questions have been answered to my satisfaction. I voluntarily agree to continue to participate in this research study until I decide otherwise. .  I will receive a copy of this signed consent document.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Subject’s Printed Name  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_  Subject’s Signature                                                                        Date (dd/mm/yyyy) Timing (hh:mm)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed Name of the Person Obtaining the Consent  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_  Signature of the Person Obtaining the Consent Date (dd/mm/yyyy) Timing (hh:mm) | |