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**Main Consent Reviewer Evaluation Form**

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| **IRB #:** Click or tap here to enter text. | **PI:** Click or tap here to enter text. |
| **Title of Study:** Click or tap here to enter text. | |
| **Primary Reviewer:** Click or tap here to enter text. | **Secondary Reviewer:** Click or tap here to enter text. |

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| **GENERAL** | **YES** | **NO** | **N/A** |
| 1. CF is presented in the LSUHSC-NO template or a format that has been approved by the administration of the IRB |  |  |  |
| 2. Document is written in language understandable to subjects |  |  |  |
| 3. Length of document is appropriate for the complexity of the study |  |  |  |
| 4. Text is in a consistent person throughout the consent form |  |  |  |
| 5. Circumstances of consent process provide prospective participant or lar sufficient opportunity to consider whether or not to participate |  |  |  |
| 6. Circumstances of consent process minimize the possibility of coercion or undue influence |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **TITLE, CONTACTS, AND SPONSOR** | **YES** | **NO** | **N/A** |
| 1. Study title in consent form matches the title of the protocol |  |  |  |
| 2. The PI is listed |  |  |  |
| 3. An emergency contact is provided |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 1: INVITATION TO BE PART OF THE RESEARCH** | **YES** | **NO** | **N/A** |
| 1. The PI and their appropriate department is listed |  |  |  |
| 2. The sponsor is listed |  |  |  |
| 3. Clear reason for why subject is eligible or being asked to participate is present |  |  |  |
| 4. Study is identified as research |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 2: IMPORTANT INFORMATION ABOUT THIS RESEARCH STUDY** | **YES** | **NO** | **N/A** |
| 1. Purpose of the study is specifically stated |  |  |  |
| 2. The eligibility criteria is described |  |  |  |
| 3. A brief description of study activities is provided |  |  |  |
| 4. The length of time the subject will be enrolled is clearly stated |  |  |  |
| 5. The most important risks are listed |  |  |  |
| 6. A brief description of the benefits is listed |  |  |  |
| 7. A brief description of alternatives is listed |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 3: WHY IS THE STUDY BEING DONE?** | **YES** | **NO** | **N/A** |
| 1. Rationale for conducting the study is provided |  |  |  |
| 2. FDA status of all drug(s) is listed |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 4: WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY** | **YES** | **NO** | **N/A** |
| 1. “Randomization” is described in lay terms |  |  |  |
| 2. The recruitment process is clearly explained |  |  |  |
| 3. CF includes a step by step description of the study events from the subject’s point of view |  |  |  |
| 4. Number/amount of blood draws is provided in household terms |  |  |  |
| 5. Dose, route and frequency of drugs to be given is stated |  |  |  |
| 6. Total duration of subject's active participation (including number and duration of any visits and follow-up periods) is provided |  |  |  |
| 7. Description of all experimental treatments & procedures is complete |  |  |  |
| 8. Description of all tests or diagnostic procedures being done for research purposes is included |  |  |  |
| 9. Explanation for collection and use of tissues (including DNA analyses) is appropriate |  |  |  |
| 10. Approximate time required to complete questionnaire(s) is stated |  |  |  |
| 11. Description about the process for audio/video recording is provided |  |  |  |
| 12. A checkbox and section for initials for audio/video recording is included |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 5: WHAT SHOULD I KNOW ABOUT GENETIC RESEARCH** | **YES** | **NO** | **N/A** |
| **This section is:**  **Applicable to this study**  **Not Applicable to this study (***move to next section***)** | | | |
| 1. Is GINA language included? |  |  |  |
| 2. If yes, description of how genetic information will be generated/used/analyzed is included |  |  |  |
| 3. If yes, language about whole genome sequencing is included |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 6: HOW MANY PEOPLE WILL TAKE PART IN THE STUDY AND HOW LONG WILL IT LAST?** | **YES** | **NO** | **N/A** |
| 1. Expected subject enrollment numbers (local and total) are provided |  |  |  |
| 2. The length of time the subject will be enrolled is clearly stated |  |  |  |
| 3. Follow-up procedures are included in the time of the study |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 7: WHAT ARE THE RISKS OF TAKING PART IN THIS STUDY?** | **YES** | **NO** | **N/A** |
| 1. All reasonably foreseeable risks are appropriately listed |  |  |  |
| 2. Risk of each drug is listed separately |  |  |  |
| 3. Risk of any required routine procedures such as blood draws and x-rays are listed |  |  |  |
| 4. Statement about unforeseeable risks is included |  |  |  |
| 5. Medical consequences of risks are explained |  |  |  |
| 6. Availability of rescue medication is stated |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 8: ARE THERE ANY BENEFITS TO PARTICIPATING IN THIS RESEARCH?** | **YES** | **NO** | **N/A** |
| 1. Description of potential benefits is appropriate and not overly optimistic |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 9: WHAT OTHER CHOICES DO I HAVE IF I DON’T TAKE PART IN THIS STUDY?** | **YES** | **NO** | **N/A** |
| 1. Subjects are informed that they may choose not to participate |  |  |  |
| 2. Subjects are informed of treatment/therapy they will receive if they don’t enroll |  |  |  |
| 3, Alternative therapies/treatments are listed |  |  |  |
| 4. Subjects are informed that they can receive this therapy off-study |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 10: HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?** | **YES** | **NO** | **N/A** |
| 1. Subject is made aware that his/her privacy will be protected |  |  |  |
| 2. Procedures for privacy protection are described and are adequate |  |  |  |
| 3. Time frame of retention of study information/samples is stated |  |  |  |
| 4. Agencies/entities/individuals who will have access to participant information and/or study results are identified and are appropriate |  |  |  |
| 5. The type of information available to agencies/entities/individuals is described and is appropriate |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 11: WILL MY INFORMATION/SPECIMENS BE USED FOR FUTURE RESEARCH?** | **YES** | **NO** | **N/A** |
| **This section is:**  **Applicable to this study**  **Not Applicable to this study (***move to next section***)** | | | |
| 1. Description of how information/specimens will be used in future research is included |  |  |  |
| 2. A checkbox and section for initials for future use is included |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 12: WILL THERE BE ANY COSTS TO ME FOR TAKING PART IN THIS RESEARCH?** | **YES** | **NO** | **N/A** |
| 1. Research and/or routine care costs covered by the sponsor is clearly delineated and is appropriate |  |  |  |
| 2. Research and/or routine care costs covered by the participant (or insurance) is clearly delineated and is appropriate |  |  |  |
| 3. Party responsible for cost of unforeseen complications is clearly delineated and is appropriate |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 13: WILL I BE PAID FOR TAKING PART IN THIS STUDY?** | **YES** | **NO** | **N/A** |
| 1. Timing and amount of subject payment is indicated and is appropriate |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 14: WHO CAN PROFIT FROM THE STUDY RESULTS?** | **YES** | **NO** | **N/A** |
| 1. Required language related to an investigator COI is provided |  |  |  |
| 2. Language describing potential commercialization of specimens is included |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 15: WHAT SHOULD I DO IF I GET SICK OR INJURED DURING THE STUDY?** | **YES** | **NO** | **N/A** |
| 1. Description of who is responsible for arranging medical care, and costs is provided |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 16: WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?** | **YES** | **NO** | **N/A** |
| 1. All investigators are listed |  |  |  |
| 2. A 24-Hour phone number is provided |  |  |  |
| 3. A research-related injury contact name and number is provided |  |  |  |
| 4. A ClinicalTrials.gov statement included |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 17: WHAT WILL HAPPEN IF I CANNOT COMPLETE THE STUDY?** | **YES** | **NO** | **N/A** |
| 1. Subject’s right to withdraw from the study, and with no loss of benefits to which he/she is entitled, is clearly stated |  |  |  |
| 2. Criteria for subject removal for medical or administrative reasons are appropriate and examples are provided |  |  |  |
| 3. Steps to be taken for safe withdrawal from the study is adequately explained |  |  |  |
| 4. Disposition of study results and specimens at the time of withdrawal is adequately explained |  |  |  |
| 5. CF states that any new information which may impact subject’s decision to continue in the study will be provided to him/her |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 18: YOUR PARTICIPATION IN THIS STUDY IS VOLUNTARY** | **YES** | **NO** | **N/A** |
| 1. Subject’s right to refuse to participate, and with no loss of benefits to which he/she is entitled, is clearly stated |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **SECTION 19: YOUR CONSENT** | **YES** | **NO** | **N/A** |
| 1. Statement confirming retention of legal rights after signing the consent is present |  |  |  |
| 2. Researchers contact statement is provided |  |  |  |
| 3. Chancellor’s contact statement is provided |  |  |  |
| 4. All appropriate signature blocks (including date lines) are present |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |