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| --- | --- | --- |
| **Project Number:** | | |
| **Project Title** [optional]: | | |
| **Principal Investigator:** | | |
| **Name of Reviewer:** | | |
| **Date of Review:** | | |
|  | | |
| **Date & Month of Submission:** | | |
|  | **Yes** | **No** |
| **Expedite Track Eligibility**  The research categorizes for posing ‘no more than minimal risk’  NOTE: Any risk ‘more than minimal’ must be ‘No’. |  |  |
| **Question/Study Idea** |  |  |
| Valid, new, and contributing knowledge to the science? |  |  |
| **Literature Review** |  |  |
| Does the Investigator provide clear background information and rational? |  |  |
| **Objectives** |  |  |
| Are clear and reflecting the study question? |  |  |
| **Methodology** |  |  |
| All study procedures qualify for the Expedite Track with a clear nature of Non-Invasive/Non- interventional? |  |  |
| **Notes on Retrieved Data/Bio-samples.**   * Collection of ARCHIVED DATA or/and STORED BIOSAMPLES for prospective GENETIC TESTING will be removed from Expedite Track and sent for Full Board. * Samples from previously approved study requires a previous KSU-IRB approval letter. * An approved copy of the approved Consent template from such studies should be provided by the Investigator. |  |  |
| **Population** |  |  |
| Will any research participants be minors (under 18 years)? |  |  |
| Is any other vulnerable population suggested? |  |  |
| Vulnerable population in disease condition? |  |  |
| Vulnerable population in healthy status? |  |  |
| **Confidentiality** |  |  |
| The Confidentiality measures are stated and the Investigator properly described what identifying data will be collected, and ensure the privacy and security of data access? |  |  |
| **Population** |  |  |
| **Will any research participants be minors (under 18 years)?** |  |  |
| Is any other vulnerable population suggested? |  |  |
| Vulnerable population in disease condition? |  |  |



|  |  |  |
| --- | --- | --- |
| **No** | **Yes** |  |
|  |  | Vulnerable population in disease condition? |
|  |  | Vulnerable population in healthy status? |
|  |  | **Confidentiality** |
|  |  | The Confidentiality measures are stated and the Investigator properly described what identifying data will be collected, and ensure the privacy and security of data access? |
|  |  | **Questionnaire/Study Tools/Data Sheet** |
| Are the study tools: Questionnaire(s), Data Sheet appropriately designed and valid for study purpose? |
| Are the study tools: Questionnaire(s), Data Sheet appropriately designed and valid for study purpose?  Are/Is there any question(s) posing ‘Sensitive material/Questions’ which can make participants unwilling to response? |
| Is/are there options to refuse to answer any response, if participants feel? |
| Identifiers are applicable to collect?  *Make sure that the Participant's Name, Medical Record Number [MRN], or Biometric Information is Not Acceptable.* |
|  |  | **Copyright Permission** |
|  |  | Required/ provided. |
|  |  | **Informed Consent**  The Consent forms must be provided where applicable, for any prospective procedure, addressing the potential participant, an adult 18 years or older or the participant's legally authorized representative. |
|  |  | 1. Provided |
|  |  | 1. Adequate |
|  |  | 1. Contains all required elements |
|  |  | 1. Language is understandable |
|  |  | 1. Statement that this is a research & participation is voluntary |
|  |  | 1. Explanation of purpose of the research |
|  |  | 1. Description of procedures involved |
|  |  | 1. Statement of confidentiality of records and who may see records |
|  |  | 1. Informed consent information and protocol information match |
|  |  | **Reviewer’s Comments or/and Suggested changes to any element of this sheet, Protocol, Study Tool, or Consent Document.** |
|  | | |

|  |  |  |
| --- | --- | --- |
| No | Yes |  |
|  |  | **OTHER ETHICAL CONSIDERATIONS**  Please mention any ethical consideration required, if any: |
|  |  | Subject’s privacy and confidentiality are maximized |
|  |  | Subject’s risk to benefit ratio |

**PROTOCOL DETERMINATION**

**☐ Approve**

**☐ Approve with required modifications**

**☐ Reject advising for major change** (*due to similarity to other project****)***

**☐ Recommend to Full Board; Justification.**

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| --- |
| **JUSTIFICATION FOR FULL BOARD RECOMMENDATION.** |