|  |
| --- |
| **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.** |