**Determination of Human Subject Research**

**Moraine Park Technical College**

**Research Integrity & Compliance Review Office, Institutional Review Board**

If there is *any* question as to whether your project is **human subject research**, please submit this form to the Moraine Park Technical College IRB department; **complete all sections** and email to: bljubenko@morainpark.edu

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| PROJECT CONTACT |  |
| Principal Investigator:Phone:Email:Alternative Contact:Department:Email:Phone: |  |
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| PROJECT  |
| Project Title:Purpose of the project:*provide a 3-5 sentence lay-language description.* |
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| PROJECT PROCEDURES |  |
| Description:Source of Data:Source of Specimens:Collection Circumstances: |  |
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| IS THIS RESEARCH ACTIVITY?  |
| **Research: A systematic investigation designed to develop or contribute to generalizable knowledge.**Do you consider this project to meet the definition of research? YES: NO: If “no” explain why: |
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| DOES THIS RESEARCH INVOLVE HUMAN SUBJECTS?  |
| Does your project include obtaining data or specimens about a living individual through intervention or interaction or by collecting personal identifying information about the individual?YES: NO:  |
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| DOES YOUR PROJECT INVOLVE THE USE OF EXISING DATA OR SPECIMENS?  |
| YES: NO: |
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If “**YES**” answer the following:

1. Do the data or specimens contain identifiable private information (i.e. the identity of the subject is or may be readily ascertained or can be associated with the information?

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| **YES** |  |
| **NO** |  |

1. Are the data or specimens coded such that a link exists that could allow the data or specimens to be identified?

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| --- | --- |
| **YES** |  |
| **NO** |  |

1. If ‘yes’, is there an agreement prohibiting the PI and their staff access to the key to the code?

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| --- | --- |
| **YES** |  |
| **NO** |  |

1. Were the data or specimens originally collected for this project?

|  |  |
| --- | --- |
| **YES** |  |
| **NO** |  |

1. Were the data or specimens originally collected during standard clinical care?

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| --- | --- |
| **YES** |  |
| **NO** |  |

1. Were the data or specimens originally collected for research purposes under an IRB approved protocol?

|  |  |
| --- | --- |
| **YES** |  |
| **NO** |  |

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| IS THIS FDA-REGULATED RESEARCH?  |
| **Does your project include testing the safety and efficacy of a drug or device in a living individual?**YES: NO:**Does your project include an *In Vitro* Diagnostic Device?**YES: NO: |
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| OTHER CONSIDERATIONS?  |
| **Does your project involve human embryonic stem cells (hESC), adult human stem cells, pluripotent cells or somatic nuclear transplantation?****YES:** **NO:****Does your project involve the use of fetal tissue?****YES:** **NO:** |
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| EXTERNAL FUNDING?  |
| **Is your project supported by external funding?****YES:** **NO”****If ‘YES’: provide a copy of the grant application, contract, agreement, etc. for this project with this form. Funding is provided from the USDA through a cooperative agreement.** |
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**Thank you for your complete application.**

**The MPTCIRB will send you a *Notice of Determination of Human Subject Research* or will contact you if more information is needed.**