Hello and thank you for accessing this form from the University of Maryland, Baltimore County Institutional Review Board web site.

Prior to submitting, please ensure that spelling and grammar are correct; this will assist in the timely review of this form during the IRB evaluation process.

Enter information by clicking the [ ]  box or typing in the **Click here to enter text.** area.

**Please go to UMBC** [**IRB website**](http://research.umbc.edu/institutional-review-board-human-subjects/) **for all up-to date guidance and information regarding the below questions.**

IRB #: Click here to enter text. Investigator(s): Click here to enter text.

Protocol Title: Click here to enter text.

Date modification is submitted: Click here to enter a date.

Select all appropriate sections that describes the modification**.** Attach copy of revised protocol application **highlighting in yellow and underline)** indicating where changes are required.**ALL modified documents must be submitted in Microsoft Word format**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| [ ] **Change in or Modifying of Protocol Title** |

|  |  |  |
| --- | --- | --- |
| [ ]   **Add** | [ ]   **Delete** |  [ ]  **Modify**  |
|  |

 |
| [ ] **Change in Procedures** |

|  |  |  |
| --- | --- | --- |
| [ ]   **Add** | [ ]   **Delete** |  [ ]  **Modify**  |
|  |

 |
| [ ] **Change in Principal Investigator** |

|  |  |  |
| --- | --- | --- |
| [ ]   **Add** | [ ]   **Delete** | [ ]   **Modify**  |
| *Indicate CITI training completion dates*  |

 |
| [ ] **Change in Study Personnel**  |

|  |  |  |
| --- | --- | --- |
| [ ]   **Add** | [ ]   **Delete** | [ ]   **Modify**  |
| *Indicate CITI training completion dates*  |

Has there any changes to any previous conflict of interest disclosure, as described by [UMBC’s Conflict of Interest](http://www.umbc.edu/research/ORPC/coi_procedures_umbc.html) policies? [ ]  Yes [ ] No [ ]  N/A  |
| [ ] **Change in Measures** |

|  |  |  |
| --- | --- | --- |
| [ ]   **Add** | [ ]   **Delete** | [ ]   **Modify**  |

*Attach copy of revisions* ***highlighting in yellow and underline.*** |
| [ ] **Change in / Add Sponsored Funding** |

|  |  |  |
| --- | --- | --- |
| [ ]   **Add** | [ ]   **Delete** | [ ]   **Modify**  |

 |
| [ ] **Change in Recruitment/Advertising** |

|  |  |  |
| --- | --- | --- |
| [ ]   **Add** | [ ]   **Delete** | [ ]   **Modify**  |

*Attach copy of revisions* ***highlighting in yellow and underline.*** |
| [ ] **Change in Number of Participants and/or Participant Selection** |

|  |  |
| --- | --- |
| [ ]   **Increase by:** Click here to enter text. | [ ]   **Decrease by:** Click here to enter text. |
| **Resulting total to be enrolled:** Click here to enter text.**Reason for Change:** Click here to enter text. |

 |
| [ ]  **Consent Process Change and/or Change in Consent Documents** |

|  |  |  |
| --- | --- | --- |
| [ ]   **Add** | [ ]   **Delete** | [ ]   **Modify**  |

*Attach a copy of the current approved consent document and a copy of the proposed document with changes* ***highlighted in yellow and underlined***  |
| [ ] **Change in Data Collection, Storage and Confidentiality** |

|  |  |  |
| --- | --- | --- |
| [ ]   **Add** | [ ]   **Delete** | [ ]   **Modify**  |

 |
| [ ] **Change in Location** |

|  |  |  |
| --- | --- | --- |
| [ ]   **Add** | [ ]   **Delete** | [ ]   **Modify**  |

 |
| [ ] **Other Change** | **Specify:** Click here to enter text. |

**Reanalysis of Risk**

[ ] This modification **does not** increase the risks to participants in the approved protocol

[ ] This modification **does** increase the risks to participants in the approved protocol

**Provide a narrative summary of all proposed modifications with a description of how the modifications affect research risks and benefits. Also describe any event or new data that precipitated the change.**

Click here to enter text.

**Electronically submit the protocol and any accompanying documents to** [**irbsubmissions@umbc.edu**](file:///%5C%5Csharedvol.ad.umbc.edu%5CDept%5CORA%5CHARPO%5CIRB%5Cirb%20forms%5Cirbsubmissions%40umbc.edu)**.**