**Protocol Modification Request**

Any proposed change to an already approved human subject research protocol, measures, or informed consent document during the period of IRB approval must be submitted using the below form to the IRB immediately for review and approval. ***An investigator cannot initiate the procedures/changes stated in the modification until IRB approval has been obtained.*** A modification to the protocol does not change the end date of the approval—this requires an Annual Continuation Report, found at <https://www.pgcc.edu/about-pgcc/institutional-information--policies/research-assessment-and-effectiveness/>.

*Examples of minor changes*

1. Administrative changes
2. Minor consent form changes
3. Minor changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods
4. Minor changes to study documents such as surveys, questionnaires or brochures
5. New study documents to be distributed to or seen by subjects that are similar in substance to those previously approved
6. Changes in payment to subjects or the amount subjects are paid or compensated that are not significant enough to affect the risk/benefit ratio of the study
7. Decrease in the number and volume of sample collections as long as they do not negatively alter the risk/benefit ratio of the study
8. Editorial changes that clarify but do not alter the existing meaning of a document
9. Addition of or changes in study personnel
10. Addition of a new study site
11. Translations of materials already reviewed and approved by an IRB

*Examples of major changes*

1. Changes that adversely affect the risk/benefit ratio of the study or specifically increase the risk to subjects
2. Changes in inclusion/exclusion criteria that impact the risk/benefit ratio of the study
3. Significant changes in study design, such as the addition of a new subject population or the elimination of a study arm
4. New risk information that is substantial or adversely affects the risk/benefit ratio of the study
5. Significant changes to the study documents to be distributed to or seen by subjects
6. New study documents to be distributed to or seen by subjects that include information or questions that are substantively different from materials already approved by the IRB

**Research Title:** Click or tap here to enter text.

**Principal Investigator Information:**

**Name:** Click or tap here to enter text.

**Email:** Click or tap here to enter text.

**Institution:** Click or tap here to enter text.

**Is the principal investigator a current employee of Prince George’s Community College?**

[ ]  **Yes** [ ]  **No**

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

Select all appropriate sections that describes the modification**.** Attach copy of revised materialsindicating where proposed changes have been made.**ALL modified documents must be submitted in Microsoft Word format**

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

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

 |
| [ ] **Change in Principal Investigator(s)** |

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

 |
| [ ] **Change in Sponsored Funding** |

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

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

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

 |
| [ ] **Change in Measures** |

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

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

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

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

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

 |
| [ ] **Change in Number of Participants and/or Participant Selection** |

|  |  |
| --- | --- |
| [ ]  **Increase**  | [ ]  **Decrease** |

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

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

 |
| [ ] **Change in Data Collection, Storage and Confidentiality** |

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

 |
| [ ] **Change in Direct Benefits for Participants (e.g., compensation)** |

|  |  |  |
| --- | --- | --- |
| [ ]   **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.

***By typing your name and date, the investigator certifies they will abide by all PGCC IRB policies and procedures and understand that no research activities will be conducted with human participants prior to obtaining the required approvals. All changes must be submitted and approved by the IRB prior to their implementation.***

Investigator’s Signature: Click here to enter text. Date: Click here to enter a date.

Faculty Advisor's Signature: Click here to enter text. Date: Click here to enter a date.