### IRB RENEWAL FORM

 

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| **SECTION A: General Information** |
| 1. | IRB Approval Number: |  |
| 2. | Project Title: |  |
| 3. | Protocol Expiration Date: |  |
| 4. | Principal Investigator(s): |  |
| 5. | Co-Principal Investigator(s): |  |
| 6. | Is this research being funded by an external funding agency? | **[ ] YES:** | **[ ]  NO**  |

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| **SECTION B: Status of Study** |
| 1. | What is the current status of your study? |
|  | [ ]  Not Started. Planning on enrollment within the next year. |
|  | [ ]  New subject enrollment still in progress. |
|  | [ ]  Enrollment closed but subjects are still involved in data collection procedures. |
|  | [ ]  Subject involvement completed; the study has progressed to the point that it only involves:  |
|  |  | [ ]  Data analysis, including analysis of identifiable private information or identifiable biospecimens |
|  |  | [ ]  Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care |
|  | [ ] \* Subject involvement completed; analyzing data and/or specimens with no identifiable information (e.g., identifiers removed from data). *\*****If you check this box, please stop and submit a Final Report form instead****. Data/specimen analysis needs renewal approval ONLY if the data/specimens include identifiable information. If only research activity remaining is analysis of de-identified data/specimens your study is considered closed for IRB purposes.* |
|  | [ ]  Other (explain):  |

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| **SECTION C: General Study Information** |
| 1. | Provide a brief summary of the study progress to date and state whether the findings are consistent with what you expected. If enrollment has not begun explain reason for delay and likelihood that subjects will be enrolled in the next year. |

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| 2. | Do you have any proposed changes/amendments to your protocol application that need to be submitted for IRB review and approval? Please indicate below and submit a separate **Modification Form** to explain the proposed changes. The modification will be reviewed for approval with this renewal. Changes may not be implemented until you receive IRB approval. |
|  | **[ ]**  | **I have modifications that need approval.**  |
|  | **[ ]**  | **No modifications at this time.** |
| 3. | Attach a copy of the current consent form(s), only if you still have active subjects. This includes assent forms, parent/guardian consent forms, verbal consent scripts, etc. Not applicable for data analysis of identifiable information. |
|  | **[ ]**  | **Documents attached:** |
|  | **[ ]**  | **Not Applicable** |

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| 4. | To your knowledge, since the last protocol approval date, has there been any new information, either through the study itself or through outside sources (e.g. literature, journal articles, conferences, etc.) that is relevant to IRB review such as information that may indicate a change in what was previously understood about the anticipated risks or benefits of the research?  |
|  | **[ ] YES** | **[ ]  NO**  |  |
|  | If YES, please summarize or attach: |

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| **SECTION D: Participants** |
| 1. | Indicate the **total number** of participants that have been enrolled **to date**. If you have multiple subject pools (e.g., parents and children) indicate how many total participants have been recruited for each SEPARATE group. |
|  | **PARTICIPANT GROUP** | **NUMBER ENROLLED** |  |
|  |       |       |  |
|  |       |       |  |
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|  | **Comments:**       |  |

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| 2. | Indicate the **anticipated number** of additional/new participants to be recruited in order to complete the study. If you have multiple subject pools (e.g., parents and children) indicate how many anticipated participants are needed for each SEPARATE group. |
|  | **PARTICIPANT GROUP** | **NUMBER NEEDED** |  |
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|  | **Comments:**       |  |

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| 3. | Provide a summary of any subject attrition since the last IRB review, and reasons for attrition, if known. |

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| **SECTION E: Adverse/Unanticipated Events** |
| 1. | Provide a summary of both any unanticipated problems and available information regarding adverse events. |

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| 2. | If an unanticipated problem or adverse event occurred, was an **Interim Report Form** submitted?  |
|  | **[ ]  NA**  | **[ ]  YES** | **[ ]  NO** |
| 3. | Have you received any complaints about the research?  |
|  | **[ ] YES** | **[ ]  NO**  |  |
|  | If YES, please describe the complaint and how it was handled: |

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| **SECTION F: Data Storage** |
| 1. | Where are your project files being stored? Indicate specific locations. *(Note: A copy must be stored on COCC’s campus.)* |

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| 2. | Have you verified the status of all project files, and confirmed they are stored in a safe and secure location? Data must be kept for at least three years after project is completed. |
|  | **[ ] YES** | **[ ] NO**  | If NO, explain: |

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| **SECTION G: Investigator Comments** |
| Please provide any additional information that may be helpful for the IRB’s review of this renewal. |

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| **SECTION H: SIGNATURES**  |
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| *By signing this form, the Principal Investigator attests that (s)he has read the information submitted for IRB review**.* |
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| **Principal Investigator (PRINT)** |  | **Signature** |  | **Date** |

**This page, signed by the principal investigator, may be submitted as a scanned PDF to the IRB Chair at** **jdowning@cocc.edu****.**