|  |
| --- |
| **Study Information** |
| DSHS IRB Number | Click to enter number. |
| Principal Investigator | Click to enter text. |
| Protocol Title | Click to enter text. |

**Complete this section.**

|  |
| --- |
| **Changes** (check all that apply) |
| [ ]  I. Principal Investigator (PI): Contact Information Update or Designate New PI [ ]  II. Research Team Member Update: Changes to the Research Team Log[ ]  III. Data or Biospecimens Relocation or Transfer: Changing or Adding Institutions [ ]  IV. Protocol or Recruitment Protocol Modification[ ]  V. Informed Consent Document Modification [ ]  VI. Study Document Changes: Recruitment Materials, Surveys, Study Instruments[ ]  VII. New Data or Biospecimens Request: Adding Variables, Changing Timeframe[ ]  VIII. Other |

**Provide concise information in the appropriate section to complete the requested change(s) checked above.**

|  |
| --- |
| 1. **Principal Investigator Update** - Contact Information Update or Designate New PI
 |
| Name | Click to enter text. |
| Organization | Click to enter text. |
| Mailing Address | Click to enter text. |
| City, State, Zip | Click to enter text. |
| Phone Number | Click to enter text. | Email | Click to enter text. |
| Secondary Contact |
| Name | Click to enter text. |
| Organization | Click to enter text. |
| Phone Number | Click to enter text. | Email | Click to enter text. |
| Are you submitting this application as a student? |
| [ ]  Yes (Enter your faculty advisor as the secondary contact if submitting as a student).[ ]  No |

|  |
| --- |
| 1. **Research Team Member Update -** Changes to the Research Team Log
 |
| List the members(s) being added and removed from the study. 1. Update and submit the Research Team Log.
2. Submit a Human Subject Research (HSR) protection training certificate for each new team member.
 |
| Click to enter text. |

|  |
| --- |
| **III. Data or Biospecimens Relocation or Transfer -** Changing or Adding Institutions |
| Detail where the DSHS/ HHSC data or biospecimens will be relocated or where a copy of the data will be transferred to as a new storage site. 1. Update the Protocol form to describe the new site, data management, and destruction plan.
2. Submit a clean and track change copy of the form.
3. Submit a certificate of destruction or other written verification from the original storage site if the data are permanently relocated to a new site.
 |
| Click to enter text. |

|  |
| --- |
| **IV. Protocol or Recruitment Protocol Modification** |
| Describe the changes made to the Protocol or Recruitment Protocol and submit a clean and track change copy of the form. |
| Click to enter text. |

|  |
| --- |
| **V. Informed Consent Document Modification** |
| Describe the changes made to the informed consent document and submit a clean and track change copy of the form. |
| Click to enter text. |

|  |
| --- |
| **VI. Study Document Changes** |
| Describe the changes made to the study document and submit a clean and track change copy of the document. |
| Click to enter text. |

|  |
| --- |
| **VII. New Data or Biospecimens Request -** Adding Variables, Changing Timeframe |
| A. Specify the new years of data and biospecimens being requested. Update the Protocol form and submit a clean and track change copy, if applicable. |
| Click to enter text. |
| B. Describe the new data variables being requested. 1. Submit an updated program data checklist.
2. Update the Protocol form and submit a clean and track change copy, if applicable.
 |
| Click to enter text. |

|  |
| --- |
| **VIII. Other** |
| Detail other changes for review. |
| Click to enter text. |