|  |  |
| --- | --- |
| **Reason for Submission (select one)** | For DSHS IRB Office Use Only |
| [ ]  Initial Review | DSHS IRB# Number |
| [ ]  Existing DSHS IRB# NumberSelect submission request from the dropdown list.Submission Dropdown List |  |
| **Project Dates** |
| Estimated Project Start Date | Click to enter a date. |
| Estimated Project End Date | Click to enter a date. |

|  |
| --- |
| **Principal Investigator** |
| 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. |
| **Authorized Signatory** |
| Please provide the contact information for a person authorized to sign the required MOU and/or DUA.  |
| 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 a secondary contact if submitting as a student).[ ]  No |

|  |
| --- |
| **Protocol Title** |
| Click to enter text. |

|  |
| --- |
| **DSHS and HHSC Program Contacts** |
| Program Name | Contact Name | Contact Information |
| Click to enter text. | Click to enter text. | Phone | Click to enter text. |
| Email | Click to enter text. |
| Click to enter text. | Click to enter text. | Phone | Click to enter text. |
| Email | Click to enter text. |
| Click to enter text. | Click to enter text. | Phone | Click to enter text. |
| Email | Click to enter text. |
| Click to enter text. | Click to enter text. | Phone | Click to enter text. |
| Email | Click to enter text. |
| **Funding Source** |
| [ ]  Federal Grant [ ]  State Grant [ ]  Another Grant [ ]  No Grant |
| Grant Number | Click to enter text. | Grant Amount | Click to enter text. |
| Agency | Click to enter text. |

|  |
| --- |
| **Subject Population** (Check all that apply) |
| Only select if the special population is the **target population and focus of the study**. |
| [ ]  Pregnant women, human fetuses, neonates[ ]  Children (17 years and younger)[ ]  Prisoners[ ]  Cognitively impaired persons |

|  |
| --- |
| **Reviews by Non-DSHS Institutional Review Boards** |
| Submit copies of other IRB determination letters. Enter “pending” if applicable. |
| Name of Organization | Determination |
| Click to enter text. | Click to enter text. |
| Click to enter text. | Click to enter text. |
| Click to enter text. | Click to enter text. |
| Click to enter text. | Click to enter text. |

|  |
| --- |
| **Acknowledgment of DSHS IRB Requirements** |
| By initialing the box next to each condition, checking the conflicts of interest box, and signing this application, I certify that I meet all requirements of the DSHS IRB. |
| Communication with Program Contact |
|  | I have communicated with the appropriate Department of State Health Services (DSHS) and Health and Human Services Commission (HHSC) program contacts to verify their support and the availability of the data and/or biospecimens for the requested timeframe. |
|  | The program contacts disclosed any relevant fees or cost reimbursement required for the requested data or biospecimens. Payment must be received before the data or biospecimens are provided. |
| Disclosure of Conflicts of Interest |
|  | Investigators and members of their research team must report immediately below if they, their spouse, or dependent children have any of the following disclosable financial interests:* Ownership interest, stock, stock options, or other financial interest of more than $10,000 that is related to the research.
* Compensation (salary, consultant payments, honoraria, royalty payments dividends, loans, or other payments or consideration with value) of more than $10,000 in the past year when aggregated for the immediate family that is related to the research.
* Proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement that is related to the research.
* Board or executive relationship, regardless of compensation, that is related to the research.
 |
| [ ]  I do not have conflict(s) of interest to disclose.[ ]  I have conflict(s) of interest to declare for myself or members of my research team and have included a Conflicts of Interest Letter in this submission. |
| Responsible Conduct of Research |
|  | I will meet exemplary standards of intellectual honesty in the formulation, conduct, reporting, and reviewing of this research study (as defined by the National Institutes of Health Office of Extramural Research <https://grants.nih.gov/policy/research_integrity/what-is.htm>). |
|  | I declare that scientific integrity includes meticulous attention to the acquisition and maintenance of the research data or biospecimens. |
|  | I will adhere to the applicable Federal laws and regulations; Texas state laws, regulations, statutes, and codes; and the Texas Health and Human Services system-wide, agency, and program policies to ensure compliance with the IRB approved protocol and the protection of the research subjects and their data, as communicated to me by the DSHS and HHSC program contact(s). |
|  | I will adhere to the DSHS Human Subject Research Protection Training requirements and ensure all my research team members also comply. |
| Principles of Data Management |
|  | The electronic data will be stored in a secured and encrypted manner meeting applicable DSHS or HHSC-specified standards. |
|  | Hard copies of all data or biospecimens will be stored in a secure location that meets DSHS or HHSC-specified standards. |
|  | All data and biospecimens will be protected against unauthorized access, disclosure, transfer, modification, reproduction, and destruction. |
|  | Data received from DSHS or HHSC will not be linked or matched to any other data without prior written permission from the DSHS or HHSC data source and approval from the DSHS IRB. |
|  | For investigators who work for federal agencies which are subject to the Freedom of Information Act and the Privacy Act, the confidential identifying data will not be released except as required by those Acts. The respective DSHS or HHSC program contacts and the DSHS IRB must be notified of any potential release, consistent with applicable law. |
| Protection of Confidential Data or Biospecimens |
|  | No DSHS or HHSC provided data or biospecimens will be used for any purpose other than that specifically stated in this application and described in the IRB-approved protocol. |
|  | The data or biospecimens provided by the DSHS or HHSC programs for this study are the property of DSHS or HHSC. Ownership or ownership interest of the data or biospecimens does not transfer to the principal investigator, project partners, research team members, organization, or the sponsor. |
|  | The data or biospecimens provided by DSHS or HHSC will be treated strictly as confidential. |
|  | All data that directly or indirectly identifies a person will not be shared with any individual outside the research team, or any other entity, agency, institution, or firm. |
|  | Data or biospecimens may not be used to discover personal identities unless prior written approval has been provided by the DSHS IRB. |
| Publication of Outcomes |
|  | Any results reported will comply with the suppression and aggregation rules specified by the program(s) or DSHS. Results will not identify any individuals, data providers, institutions, or firms unless prior written approval has been provided by the DSHS or HHSC data source and the DSHS IRB. |
|  | All reports and other materials prepared for publishing from research using the data and biospecimens will be submitted to the program contact(s) and the DSHS IRB once they are accepted by the publisher. |
|  | DSHS or HHSC will be credited as the source of the data or biospecimens as specified by the program(s). No statement will be made indicating or suggesting that interpretations drawn from DSHS or HHSC data and biospecimens are those of DSHS or HHSC. |
| Data Destruction |
|  | A certificate of destruction or other written verification will be submitted to the IRB when the data or biospecimens are no longer needed, such as data used as an intermediary linking step or variables no longer needed after initial analysis. The destruction process used will meet DSHS or HHSC-specified standards. |
|  | At the end of the research study, any remaining data or biospecimens provided by DSHS or HHSC will be destroyed in the manner described in the IRB-approved protocol unless specific prior written permission is granted by DSHS or HHSC for their retention. Upon completion, a certificate of destruction or other written verification will be submitted to the IRB. |
| Final Report |
|  | A Final Report of the study will be submitted to the DSHS IRB and program contact(s) within 60 days of completion of the study. |
| Submission |
|  | This application includes all the required and applicable documents outlined in the submission checklist. |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Principal Investigator Signature |  | Date |