|  |
| --- |
| Supplemental Form: Biospecimens |

|  |
| --- |
| Submit this form in addition to the IRB Research Proposal in IRBaccess when a study involves collection of biospecimens. |

|  |
| --- |
| Study Number |
| Click or tap here to enter text. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Sample Identification | | | | | | |
| Select all of the types of samples that will be collected as part of this study. | | | | | | |
|  | Amniotic Fluid | |  | Blood |  | Buccal Smears |
|  | Saliva | |  | Tissue |  | Urine |
|  | Other: Click or tap here to enter text. | | | | | |
|  | None of the Above | | | | | |
| Select all of the methods of sample collection that will be utilized in this study | | | | | | |
|  | Blood collected at the same time as nonresearch blood collections | |  | Individual needle stick(s) |  | Indwelling catheter placed solely for this study |
|  | Unused blood originally drawn for clinical purposes | |  | Other (describe here): Click or tap here to enter text. | | |
| Select yes or no for each of the following and answer the appropriate follow-up questions. | | | | | | |
| Select | | Samples will be used for pregnancy tests. | | | | |
| If Yes | | Describe procedures regarding how positive pregnancy results are communicated to the participant. If minors are involved specify any procedures specific to minor populations. | | | | |
| Click or tap here to enter text. | | | | |
| Select | | Samples will be used to screen or document alcohol or illicit drug use. | | | | |

|  |  |
| --- | --- |
| Sample Collection Method | |
| *Describe how the samples will be collected and the collection schedule for each type of sample.*  *Additional sections may be generated by clicking the + button to the right of the table while its contents are selected. Click in the table below to access the Repeating Section Content Control.* | |
| Sample Name/Type: | Click or tap here to enter text. |
| The procedures that will be followed to collect the sample | |
| Click or tap here to enter text. | |
| The role(s) of the individuals who will collect the sample | |
| Click or tap here to enter text. | |
| The volume/size range of the sample | |
| Click or tap here to enter text. | |
| The timing and frequency of sample collection | |
| Click or tap here to enter text. | |

|  |  |  |
| --- | --- | --- |
| Genetic Testing | | |
| Select | Genetic testing will be conducted on the samples. | |
| If genetic testing will occur, answer the following. | | |
| Identify and describe the conditions (e.g., diabetes, schizophrenia) for which the DNA is collected. | | |
| Click or tap here to enter text. | | |
| Select | Is the genetic component of the study optional (i.e., participants can take part in the research without participating in the genetic testing)? | |
| Select | Will any tests be conducted that could create clinically relevant findings?  If yes,identify conditions that could be treated or where the participant could benefit from genetic counseling. Click or tap here to enter text. | |
| Select | Will genetic test results, including paternity, be provided to the participants? | |
| If Yes | Select | Will tests be run in a CLIA-certified laboratory? |
| Select | Will participants have the option to decline results? |
| Describe the procedure for providing results to participants: | |
| Click or tap here to enter text. | |
| Describe how participants might access genetic counseling for assistance in understanding the implications of genetic testing results. | |
| Click or tap here to enter text. | |
| Describe any costs to participants (e.g., for genetic counseling). | |
| Click or tap here to enter text. | |
| If No | If results will not be provided, explain why not: | |
| Click or tap here to enter text. | |
| Select | Will participants have the option to request that samples and/or test results be withdrawn in order to prevent further analysis, reporting, and/or testing for this study? | |
| If Yes | How will participants be informed of how to withdraw samples or data? | |
| Click or tap here to enter text. | |
| How will participants be informed that their request has been granted? | |
| Click or tap here to enter text. | |
| Select | Will participants be able to continue with non-genetic components of the study? |
| Select | Will the DNA be stored for use in future research? | |
| *UT strongly suggests that research biorepositories be submitted to the UT IRB as a separate study, which allows multiple studies to contribute data and samples and allows investigators to close collection studies once the collection phase and analysis of identifiable data/specimens is complete.* | | |
| Select | Will the samples be identifiable directly or with a code? | |
| If Yes | Select | Is it possible that specimens may be de-identified and used for future research or be given to another investigator for future research without additional consent? |
| If Yes | The informed consent must include the following statement:  “We will share your data with other researchers for future research studies that may be similar to this study or may be very different. The data shared with other researchers will not include information that can directly identify you.” |
| If No | The informed consent must include the following statement:  “The data that we will collect about you will not be shared with any other researchers..” |
| Select | Is it possible the research might include whole genome sequencing? | |
| Select | Is it possible that biospecimens, even if de-identified, may be used for commercial profit? | |