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| APPLICATION FORM |

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| Submit this form in IRBaccess when seeking determination for human subject research using secondary data or biospecimens. |

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

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| Principal Investigator | | | |
| Name | Position | UT EID | E-mail Address |
| First Last | Title | XXX## | j.doe@utexas.edu |

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| Primary Point of Contact (if different from PI) | | | |
| Name | Position | UT EID | E-mail Address |
| First Last | Title | XXX## | jdoe@utexas.edu |

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| *Additional Research Staff* | |
|  | Research staff other than the principal investigator will conduct human subject research. |
| *If additional personnel will be engaged in conducting human subject research, complete and upload the* [*Research Personnel Form*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-Personnel-Form.docx)  *Engaged in human subject research is defined as contact or interaction with research participants through informed consent process, data collection, and analysis of or access to identifiable research data.* | |

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| Funding and Regulatory Oversight | | | | | |
|  | NIH |  | Dept. of Defense |  | Dept. of Education |
| *Complete* [*IRB Supplemental Form -DoD*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-DoD-1.docx) |
|  | Dept. of Energy |  | Dept. of Justice |  | Bureau of Prisons |
|  | Other Federal Agencies: Click here to enter text. | | | | |
|  | Industry/Private Sponsor: Click or tap here to enter text. | | | | |
|  | UT Funding Account Number: Click or tap here to enter text. | | | | |
|  | Other External Funding: Click or tap here to enter text. | | | | |
| OSP: ### | | | | | |

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| Study Information |
| Briefly describe the study procedures. |
| Click or tap here to enter text. |

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| Secondary Data or Specimens | | |
| Select | The data or specimens have been or will be collected for purposes unrelated to the proposed study. | |
| Select | The researcher will collect Identifying information as part of this study. | |
| If yes | List below all the identifiers that the researcher will obtain even if the investigator plans to eventually make the data or specimens anonymous. Include information, which can be linked directly or indirectly to the subjects. | |
| Click here to enter text. | |
| Select | You will obtain, use, or disclose Patient Health Information (PHI). | |
| *If yes, complete the* [*IRB Supplemental Form - PHI*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-PHI.docx)*.* | |
| Select | The researcher plans to use secondary data or specimens that already exist at the time or prior to this IRB submission. | |
| Select | The researcher plans to use secondary data or specimens that do not already exist at the time of this IRB submission. | |
| Select | The secondary data or specimens are publicly available open data that can be freely used, reused and redistributed by anyone. | |
| If no | Describe the restrictions that apply to this data source (*e.g.*, data access requires login). | |
| Click here to enter text. | |
| Select | The researcher will have the ability to re-identify participants. | |
| Select | There is a Material Transfer Agreement (MTA) or Data Use Agreement (DUA) in place. | |
| *If yes, upload a copy of MTA or DUA to IRBaccess* | |
| Select | Subjects provided consent for their participation in research when the data or specimens were originally collected. | |
| Select | If yes, does the consent form authorizes researcher to share data or specimens. |
| Describe the source and nature of data or specimens you will obtain. Provide information about where the data or specimens will come from (e.g., pathology lab, commercial source) and what type of data or specimens you will obtain. | | |
| Click here to enter text. | | |

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| Research Participant Information |
| Provide information about the subject population (*e.g.*, including age, gender, inclusion/exclusion criteria, and disease state). |
| Click or tap here to enter text. |

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| Total Sample Size | |
| Total number of subject records or samples | N = ### |
| Sample size rationale | Provide justification for the sample size and it is adequate for answering the research question(s). |
| Click or tap here to enter text. |

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| Waiver or Alteration of Informed Consent | |
| To approve a waiver of informed consent, all of the following criteria must be justified by the research. Provide a protocol specific justification for each. | |
| The research involves no more than minimal risk to the subjects. | Provide a protocol specific rational. |
| Click or tap here to enter text. |
| The waiver or alteration will not adversely affect the rights and welfare of the subjects. | Provide a protocol specific rational. |
| Click or tap here to enter text. |
| The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining informed consent is required and not just impracticable to obtain consent). | Provide a protocol specific rational. |
| Click or tap here to enter text. |
| If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. | Provide a protocol specific rational. |
| Click or tap here to enter text. |

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| Confidentiality and Data Security Plan |
| Describe how you will protect the confidentiality of data or specimens.  Include:   * Where you will store data or specimens * Who will have access to data or specimens * Data and specimen retention and destruction timelines |
| Click here to enter text. |
| Data or Specimen Sharing (if applicable) |
| Describe the process for sharing of data or specimens outside of the immediate study team. |
| Click or tap here to enter text. |