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| UCSD Human Research Protections Program **Secondary Use of Data, Records, and/or Biospecimens**  (Enter text and answer questions in the **areas** provided on the right side of the form) | |
| **1. PROJECT TITLE** | |
| |  |  | | --- | --- | | *Ensure this title matches the title entered on the Facesheets.* | Los Angeles County ASsessment of Phylodynamics to Improve Resource Equity: LAC ASPIRE | |

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| **2. PRINCIPAL INVESTIGATOR** |
| |  |  | | --- | --- | | *Ensure PI name is entered and all other research team members are included in* ***item 12.*** | Susan Little | |

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| **3. FACILITIES** |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | *a) Which entity/institution(s)’ data/records/biospecimens will the UCSD and/or RCHSD project team access or obtain?*  *(Select* ***all*** *that apply)*  *If another entity/institution(s) will provide data/records/biospecimens for the project, provide detail in* ***item 4.*** |  | UCSD |  | RCHSD | |  | Other: County of Los Angeles | | | | *b) Where (at which entity/institution(s)) will the data/records/biospecimens be used, retained, and/or analyzed?*  *(Select* ***all*** *that apply)*  *If another entity/institution(s) will use, retain, and/or analyze the project biospecimens/data/records, provide detail in* ***item 4.*** |  | UCSD |  | RCHSD | |  | Other: Click or tap here to enter text. | | | |

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| **4. RESEARCH DESIGN AND METHODS** |

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| |  |  |  |  |  | | --- | --- | --- | --- | --- | | 1. *Will the project involve secondary use of existing:* |  | Data/records | | | |  | Biospecimens | | | |  | Both data/records and biospecimens | | | | 1. *Briefly describe the following:*  * *Project purpose/Specific Aims;* * *Population, inclusion/exclusion criteria, and date-range of data/records/biospecimens to be used;* * *Sample-size, and how derived;* * *Specific data/variables collected and/or received.* | **Specific Aims: Aim 1 (IDENTIFY). Identify populations that are the highest priority for HIV prevention efforts (these data will inform the epidemic model used in Aim 2); Aim 2 (ALLOCATE). Develop a user-friendly dynamic transmission model that will project the impact of alternative strategies for the optimal allocation of resources to LAC HIV prevention programs (these data will project health outcomes and cost-effectiveness); and Aim 3 (ENGAGE). Engage key stakeholders to develop a process to guide project outcomes and build capacity at the LAC Health Department for data analysis that incorporates Aim 1 and 2 methods.**  **Population, sample size, etc.: Research materials for the proposed study will include historically and prospectively collected HIV surveillance data (from approximately 2007-2027) and prospectively collected HIV-1 recency data (collected from 2022 to 2027). Secondary analyses of these data will be performed. The work conducted under AIM 3 does not constitute human subjects research.** | | | | | 1. *Will the project use data/records/biospecimens for FDA-regulated research, e.g., testing an in-vitro diagnostic device (IVD)?*   ***(If Yes****, describe the FDA-regulated product)* |  | Yes |  | No | | Click or tap here to enter text. | | | | | 1. *Will this project involve?*   ***Note:*** *“Direct access/collection” is NOT the direct initial prospective collection of data/biospecimens from subjects.* |  | Only direct access/collection of data/biospecimens collected for other purposes (already existing) | | | |  | Only receipt of data /biospecimens provided to the project team by some other source (**Skip to item 4g**) | | | |  | Both direct access/collection and receipt | | | | 1. ***If collecting via direct access,*** *select collection method.*   *(Select* ***all*** *that apply)* |  | Direct access by project team member(s) | | | |  | Slicer/Dicer use by project team member(s) (Note: Epic user-access rights pertain) | | | |  | Other: Click or tap here to enter text. | | | | 1. ***If collecting via direct access,*** *select data source(s).*   *(Select* ***all*** *that apply)* |  | Student records | | | |  | Medical records (e.g., EPIC EMR) | | | |  | UCSD/RCHSD research records and/or biospecimens: Click or tap here to enter text. | | | |  | Non-UCSD/RCHSD research recordsand/orbiospecimens (enter project title(s)): Click or tap here to enter text. | | | |  | Other: Click or tap here to enter text. | | | | 1. ***If receiving data and/or biospecimens,*** *select source.*   *(Select* ***all*** *that apply)* |  | [DECS](https://healthdata.ucsd.edu/decs/) (previously CDWR) | | | |  | Data Registry(ies) (name(s)/UCSD protocol number(s): Click or tap here to enter text. | | | |  | Biospecimen Repository(ies) (names/UCSD protocol number(s): Click or tap here to enter text. | | | |  | Another research protocol (project title/UCSD protocol number): Click or tap here to enter text. | | | |  | Another entity/institution (name description): Los Angeles County (LAC) Division of HIV and STD Programs (DHSP) at the Department of Public Health (DPH) | | | | 1. ***If receiving data/records/biospecimens****, in* what format will they be provided?   *(Select* ***one*** *option; if received from multiple sources, may select more than one option and provide description)*  ***Coded*** *= Labelled with a code, with linkage to identifiers (code-key) retained.*  ***De-identified*** *= All identifiers permanently removed, no linkage (code-key) to identifiers.* |  | Readily identifiable - person identifiable information included | | | |  | Not readily-identifiable:  Coded (**Complete item 4i**)  De-identified by source  HIPAA Limited Data Set (<https://privacyruleandresearch.nih.gov/pr_08.asp#8d>) | | | | All dates will be manipulated using a coding algorithm retained within DHSP such that ready identification of days of infection, date of birth or other dates is not possible by the end user (UCSD). | | | | | 1. ***If receiving coded data/records/biospecimens****, will* ***any*** *of these additional protections be in place?*   *(Select* ***one option****; if received from multiple sources, may select more than one option and provide description)* |  | PI and source of data/records/biospecimens will enter into an agreement prohibiting release of code-key, e.g., a DUA (Data Use Agreement)/MTA (Material Transfer Agreement) | | | |  | Source of data/records/biospecimens has IRB-approved repository/bank policies and procedures prohibiting release of the code-key | | | |  | Source of data/records/biospecimens is bound by other legal requirements prohibiting release of the code-key | | | |  | Other ways in which the data/records/biospecimens are considered “not readily-identifiable” | | | | Geographic locations will be limited to zip codes. Where fewer than 5 participants are within a single zip code the data will not include zip code. All dates are manipulated using a coding algorithm retained within LAC such that ready identification of days of infection, date of birth or other dates is not possible by the end user (UCSD). | | | | | 1. ***If “Medical Records” selected in item 4f****, specify* ***what records*** *will be accessed.*   *(Select* ***all*** *that apply, ensuring* ***item 4a*** *justifies the information to be accessed.)*  ***Note:*** *Only the “minimum necessary” participant identifiers/sensitive information shall be collected.* |  | History and Physical Exams |  | Consultations | |  | Progress Notes |  | Discharge Summary(ies) | |  | Ambulatory Clinic Records |  | Emergency Dept. Records | |  | Lab and Pathology Reports |  | Imaging Reports/Studies | |  | Operative Reports |  | Other Test Reports | |  | Financial Records |  | Dental Records | |  | Drug/alcohol abuse diagnosis/treatment information |  | Genetic testing/treatment information | |  | Entire Medical Record |  | Psychological Tests | |  | Other: Click or tap here to enter text. | | | | | 1. *Will the records selected in* ***item 4j*** *include information in the following categories?*   *(****If Yes****, select* ***those*** *that apply)* |  | Yes:  Mental health diagnosis/treatment  HIV/AIDS testing/treatment | | | |  | No | | | | 1. ***If “Medical Records” selected in item 4f or “DECS” selected in item 4g****, specify* ***what identifiers*** *will be* ***accessed/recorded//provided*** *with the data collected.*   *(Select* ***all*** *that apply)*  ***Note:*** *Only the “minimum necessary” participant identifiers/sensitive information shall be collected.* |  | Names |  | Medical record numbers (MRN) | |  | Account numbers |  | Health plan beneficiary numbers | |  | Social Security numbers |  | Certificate/license numbers | |  | Phone numbers |  | Fax numbers | |  | All elements of dates, except year, (including birth date, admission date, discharge date, treatment dates, date of death, etc.) |  | Address and/or equivalent geocodes (including street address, city, county, precinct, zip code) | |  | Any ages over 89 years and elements of dates (including year) indicative of such age, except if combined into a single category, e.g., 90 and above |  | Full face photos or comparable images and/or Biometric identifiers (including finger/voice prints) | |  | E-mail addresses |  | URLs / IP addresses | |  | Vehicle identifiers |  | Device ID and/or serial numbers | |  | Any other unique identifying number, characteristic, or code: Click or tap here to enter text. | | | |

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| **5.** **SECURITY AND CONFIDENTIALITY PROVISIONS** |

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| 1. *Will there be any contact with the individuals whose information will be accessed or recorded for the current project?*   ***If Yes****, describe the purpose of the contact and how it will occur.* |  | Yes |  | | No |
| Click or tap here to enter text. | | | | |
| 1. *Confirm only the “minimum necessary” information will be collected (especially identifiable/sensitive information).* |  | Yes | |  | No |
| 1. *How will the data/records/biospecimens be* ***stored while used*** *in the project?*   *(Select* ***one*** *option; if both collected and received, or if received from multiple sources, may select more than one option and provide description)*  ***Coded*** *= Labelled with a code, with linkage to identifiers (code-key) retained.*  ***De-identified*** *= All identifiers permanently removed, no linkage (code-key) to identifiers.* |  | Coded, identifiers fire-walled/access restricted and later deleted, i.e. use of:  [REDCap](https://healthdata.ucsd.edu/redcap/)  [Velos](https://healthdata.ucsd.edu/velos/)  Other: AWS HIPAA-compliant cloud infrastructure hosted by UCSD | | | |
|  | Coded, identifiers retained separately from study data and later deleted | | | |
|  | De-identified at time of collection/receipt | | | |
| Click or tap here to enter text. | | | | |
| 1. *When will identifiers (such as those listed in item 4l above) be destroyed?*   *(Select* ***one*** *option)* |  | No identifiers used/collected/received | | | |
|  | Destroyed upon collection/receipt of data/bio-specimens | | | |
|  | Destroyed after calculation of a specific measure/data point, e.g. retaining date of birth in the research file until age at a specific time-point is calculated:  Enter description here. | | | |
|  | Destroyed upon publication of study results | | | |
|  | Destroyed at study closure | | | |
|  | Not destroyed; retained in research file(s) (provide justification): Click or tap here to enter text. | | | |
| 1. *Indicate the overall provisions for security and confidentiality of* ***non-electronic*** *project biospecimens/data/records:*   *(Select* ***all*** *that apply)* |  | No non-electronic data/records/biospecimens will be collected  **(If selected must complete item 5f)** | | | |
|  | Appropriate project team training (including CITI Completion) | | | |
|  | Restricting access of research data to project team | | | |
|  | Locked file cabinet/room limited to authorized project team members | | | |
|  | Locked lab/refrigerator/freezer limited to authorized project team members | | | |
|  | Coding of biospecimens/data/records, with separate storage of a code-key | | | |
|  | Other: Click or tap here to enter text. | | | |
| 1. *Indicate the provisions for security and confidentiality of* ***electronic*** *project data/records:*   *(Select* ***all*** *that apply)* |  | No electronic data will be collected  **(If selected must complete item 5e)** | | | |
|  | Appropriate project team training (including CITI Completion) | | | |
|  | Use of [VRD (Virtual Research Desktop)](https://healthdata.ucsd.edu/vrd/) | | | |
|  | Use of [REDCap](https://healthdata.ucsd.edu/redcap/)  [Velos](https://healthdata.ucsd.edu/velos/) | | | |
|  | Encryption of research files | | | |
|  | Encryption of research devices (computers, external hard drives, cell phones, or other portable media) | | | |
|  | Password protection of research data files/records | | | |
|  | Password protection of research devices (computers, external hard drives, cell phones, or other portable media) | | | |
|  | Secure network server for research data/record storage, i.e., OneDrive | | | |
|  | Computer(s) not connected to server/internet | | | |
|  | Other: AWS HIPAA-compliant cloud infrastructure hosted by UCSD | | | |
| 1. *Describe who will control access to biospecimens/data/records, including identifiers, and how access will be controlled.* | LA County (LAC) will control access to identifiers. Only persons authorized within LAC will have access to the codebook and identifiers. Within UCSD, only study personnel will have access to the coded project data. Access will be controlled by the project data manager Dr Nadir Weibel and the PI Susan Little. | | | | |

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| **6.** **DATA AND/OR BIOSPECIMEN SHARING** |

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| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | 1. *Will the data/records/biospecimens accessed/collected/received for the current project be disclosed, or used for any other purpose?*   *(Select* ***all*** *that apply)* |  | No **(Skip to item 7)** | | | | |  | Yes, for the current project, i.e., with a multi-site collaborative project or study sponsor | | | | |  | Yes, for additional future research outside of the current project/project aims. | | | | | 1. ***If project data/records/biospecimens will be disclosed/used****, describe who will receive the data, records, and/or biospecimens.*   *(Select* ***all*** *that apply)* |  | Current project personnel | | | | |  | Current project collaborator(s) (coordinating/lead site) or study sponsor: Click or tap here to enter text. | | | | |  | Other UCSD researcher(s): Click or tap here to enter text. | | | | |  | Non-UCSD researcher(s): Click or tap here to enter text. | | | | |  | Other (personnel/institution/sponsor):Click or tap here to enter text. | | | | | 1. ***If project data/records/biospecimens will be disclosed/used****, describe what specific data, records, and/or biospecimens will be disclosed/used.* | Future research may include use of data pertaining to demographics, STI, geographical spread and HIV cluster outcomes | | | | | | 1. ***If project data/records/biospecimens will be disclosed/used****, describe how the data and/or biospecimens will be made available/transferred, i.e., all HIPAA identifiers removed, as a Limited Data Set with Data Use Agreement.* | Future research will only use data that has had all HIPAA identifiers removed as per the data use agreement with LAC | | | | | | 1. *I****f project data/records/biospecimens will be disclosed/used for additional future research****, i.e., creation of a registry/repository, describe the process by which requestor(s)/recipient(s) will “apply” to obtain data/records/biospecimens.*   *Include who will manage access and how requesting researchers’ IRB approval or exempt/not human subject research determination will be verified prior to release of data/records/biospecimens.* | Future research proposals will be evaluated by the PI Susan Little. Proposed projects will need to demonstrate the determination as huma subject research/exempt as part of the proposal and appropriate IRB paperwork demonstrated prior to data release/access. | | | | | | 1. *I****f project data/records/biospecimens will be disclosed/used for additional future research****, will results from the future research be returned* ***for inclusion in the registry/biorepository?***   ***If Yes****, describe how this**will be managed?* |  | | Yes |  | No | | | Click or tap here to enter text. | | | | | |

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| **7.** **INFORMED CONSENT AND HIPAA AUTHORIZATION** |

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| |  |  |  | | --- | --- | --- | | 1. *Provide detail regarding subject consent and/or HIPAA authorization.*   *(Select* ***one*** *option at right; if received from multiple sources, may select more than one option and provide description in* ***item 7b****)* |  | A waiver of consent (and assent, if appropriate) and/or HIPAA authorization is required/requested  **(If only requesting waivers, skip to item 8)** | |  | Consent/permission/assent and/or HIPAA authorization obtained in source/originating project and consent form includes/d provisions for data/record/biospecimen use in additional future research. | | 1. ***If consent and/or HIPAA authorization obtained in source/originating project****, provide a description here.* | Click or tap here to enter text. | | |

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| **8. WAIVER OF INFORMED CONSENT AND WAIVER OF HIPAA AUTHORIZATION** |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Your answers to the following items will be assessed to ensure this project fulfills all requisite criteria in order to grant any requested waivers of informed consent** (and assent, if appropriate) **and/or HIPAA Authorization:** | | | | | | 1. *Confirm that this project presents no more than minimal risk to the individuals whose information will be accessed.*   ***Minimal risk =*** *The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests* |  | Yes |  | No | | 1. *Indicate why the waivers would not adversely affect the rights and welfare (including privacy rights) of the individuals whose information will be accessed and/or collected:*   *(Select* ***all*** *that apply)* |  | Project will not affect individual’s clinical care | | | |  | Adequate subject/data confidentiality protection measures used | | | |  | Other: Click or tap here to enter text. | | | | 1. *Describe why the research project could not practicably be carried out without using identifiable information and/or biospecimens.* | The UCSD component of the project will never handle protected health information. Results from the UCSD component of the project may be used by LAC for legitimate public health interventions. This will include using the codebook retained at LAC to identify individuals and conduct standard of care public health interventions. | | | | | 1. *Indicate why these research procedures could not practicably be carried out without the waivers:*   *(Select* ***all*** *that apply)* |  | Obtaining consent and/or HIPAA authorization would bias or impact the statistical significance of the data obtained | | | |  | Those under study are unlikely to return for clinically indicated further treatment | | | |  | Those under study are no longer seen at UCSD/RCHSD | | | |  | Those under study are likely to have moved out of the area | | | |  | Those under study are likely to have passed away | | | |  | Other: Individuals in the project are not seen by the study personnel and most will not receive care at UCSD. Many individuals may have passed away or moved away from the area. Many will not have contact details readily available. | | | | **If requesting waiver of HIPAA authorization you must be able to answer “Yes” to the following:** | | | | | | 1. *Confirm that the plan to protect identifiers from improper use and disclosure is provided in* ***item 5.*** |  | Yes |  | No | | 1. *Confirm that the plan to destroy the identifiers at the earliest opportunity is provided in* ***item 5.*** |  | Yes |  | No | |

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| **9. POTENTIAL RISKS** |

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| |  |  | | --- | --- | | *Describe and assess the likelihood and seriousness of loss of confidentiality (e.g., risks to employability, insurability, reputation) or any other risks.* | The UCSD component of this project never handles PHI. However, a codebook for participant identification is retained by LAC meaning there is a theoretical risk of loss of confidentiality. LAC are bound by their own set of data requirements to prevent loss of confidentiality.  Overall, the risk of loss of confidentiality is thought to be minimal. | |

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| **10. POTENTIAL BENEFITS** |

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| |  |  | | --- | --- | | 1. *Describe the potential benefits to subjects (individuals whose data/records/biospecimens will be accessed and/or used).*   *If there is no subject benefit this must be stated.* | There is no expected direct benefit to individuals whose data will be accessed. | | 1. *Describe the potential benefits of this research to science and society in general, i.e. the benefit of the knowledge to be gained.* | There is expected benefit of this project. Data produced through LAC ASPIRE will be used directly for public health interventions to reduce the transmission of HIV in San Diego resulting in both health benefits and cost benefits to society. Analysis of the data may provide further insight into patterns of HIV transmission and risk factors that may provide future transmission prevention benefit. | | |
| **11. FUNDING AND CONFLICT OF INTEREST** |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | 1. *Is this research project funded?*   *(Select* ***only those that apply****)* |  | Unfunded/Internally (UCSD/RCHSD Department or ORU) funded | | |  | |  | Grant funded (federal or other non-profit) (Provide funder name (e.g. NIH, NSF, DoD), type of grant, grant number; and indicate whether the grant is a UCSD/RCHSD award or sub-award/contract): Click or tap here to enter text. | | |  | |  | Commercially sponsored (Sponsor or PI-initiated) (Provide sponsor name and describe the role(s) of PI/co-investigator(s) in project design and initiation, and describe the Sponsor’s access to data. Submit the Master Protocol separately): Click or tap here to enter text. | | |  | |  | Other: Click or tap here to enter text. | | |  | |  | |  | | 1. *Does any member of the project team have a potential* [*conflict of interest*](https://blink.ucsd.edu/sponsor/coi/quickreference.html)*?*   ***If Yes****, provide description and* [*submit for IRC review*](https://blink.ucsd.edu/sponsor/coi/irc.html) |  | Yes |  | No | | Click or tap here to enter text. | | | |  |  |  |  |  | | --- | --- | --- | --- | | **12. GENOMIC DATA SHARING (GDS)** | | | | | 1. *Is the project subject to the* [*NIH GDS Policy*](https://osp.od.nih.gov/scientific-sharing/policies/)*?*   *(****May select******more than one option*** *and provide description in* ***item 11b*** *below.)* |  | No **(Skip to item 13)** |  | | |  | Yes, project is NIH funded and subject to the policy |  | | |  | Yes, PI will voluntarily post genomic data to NIH repository | |  | Yes, biospecimens or genomic data will be shared with downstream projects and those projects might be subject to the policy |  | | | 1. ***If the project/downstream projects are/may be subject to the NIH GDS Policy****, include a description of the project GDS plan.* | Click or tap here to enter text. | |  |  |  |  | | --- | --- | --- | | **13. RESEARCH PROJECT TEAM** | | | | *List all project team members, their credentials, department, and institutional affiliation(s), and briefly describe their study responsibilities, i.e., collection of data/records/biospecimens, project database management, management of access to data/specimens, data analysis, management of registry/biorepository (including review of data/specimen requests, distribution of data/specimens, etc.).*  *This description should specify which individuals are privileged/certified, and at what sites, to perform the procedures in the protocol.*  *Note: IRB approval does not override limits on privileges.* | Susan Little MD – PI – UCSD, department of medicine. Responsible for overall administration, fiscal and scientific management of the subcontract.  Natasha Martin DPhil – UCSD, department of medicine. Expertise in HIV epidemic modelling. Will develop the dynamic models of HIV incidence in San Diego County.  Joel Wertheim PhD – UCSD, department of medicine. Expertise in viral molecular evolution and epidemiology. Oversee the analysis of HIV genetic sequence data.  Antoine Chaillon, MD, PhD - UCSD, department of medicine. Expertise in molecular biology, virus evolution, phylogeographic analyses, and statistics.  Sanjay Mehta MD – UCSD, department of medicine. Will ensure that accurate and appropriate data is transferred to the UCSD database. Data analysis of molecular data.  Nadir Weibel PhD – UCSD, department of medicine. Expertise in developing tools, techniques and infrastructure to support multimodal systems for healthcare.  Adriane Wynn, PhD - UCSD, department of medicine. Expertise in improving public policies related to maternal and child health, HIV, and sexually transmitted infections (STIs) by providing unbiased estimates of the effect of policy changes on economic and health outcomes.  Christy Anderson – UCSD, department of medicine. Serves as the principal statistician with over 20 years of experience in the statistical analysis of biomedical data.  Kathleen Bamburg – UCSD, department of medicine. Will serve as project manager and will coordinate communications and regular meetings for all project partners, will oversee the execution of appropriate programmatic contracts, such as data use agreemets  Joseph Lencioni – UCSD, department of medicine. IRB and regulatory affairs administrator who will ensure appropriate approvals, regulatory training and certification for study personnel. | |
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Version date: 3/17/2020