 Human Subjects Research Committee

 hsrc@dmh.lacounty.gov

**PART I - HUMAN SUBJECTS RESEARCH COMMITTEE**

**APPLICATION FORM**

|  |
| --- |
| 1. **Information**
 |
| Protocol Title: | Click here to enter text. |
| Protocol Number: | **COMPLETED BY HSRC ADMIN. ONLY** |
| Principal Investigator (PI): | Click here to enter text.  |
| PI’s Mailing Address, Name of Institution, and Department | Click here to enter text. |
| PI’s Telephone, Fax, and E-mail: | Click here to enter text. |
| Primary ContactName: | Click here to enter text. |
| Primary Contact Telephone and E-mail: | Click here to enter text. |
| Anticipated Start and Finish Dates: | Click here to enter dates. |
| Funding Source/Grant Amount:(If none, please indicate:“Unfunded”) | Click here to enter text. |
| External Institutional Review Board (IRB) Review:List IRB Institution(s) | Click here to enter text. |
| Date of Initial Submission: | Click here to enter a date. |

|  |
| --- |
| 1. Los Angeles County Department of Mental Health (LACDMH) Involvement

Check all that apply. |
| [ ]  Data Provision *(specify what data & the source)* | Click here to enter text. |
| [ ]  Study Participant Recruitment *(explain)* | Click here to enter text. |
| [ ]  Use of LACDMH Facilities and Other Resources *(specify place & activity)* | Click here to enter text. |
| [ ]  LACDMH Staff *(specify staff & activity)* | Click here to enter text. |
| [ ]  Directly Operated Program *(specify site, staff, & activity)* | Click here to enter text. |
| [ ]  Legal Entity (LE) Contracted Agency *(specify site, service area, staff, & activity)*  | Click here to enter text. |
| [ ]  Specific Benefits to LACDMH *(explain)* | Click here to enter text. |
| [ ]  Other *(explain)* | Click here to enter text. |
|  |
| Submit the COMPLETED and SIGNED application along with ALL relevant document(s) electronically to the Human Subjects Research Committee (HSRC) at hsrc@dmh.lacounty.gov.  |

|  |  |
| --- | --- |
|  | PersonnelName all individuals involved in the Design, Conduct, Analysis, or Reporting of Project-Related Activities |
| Name and Bureau/ Division | LACDMH Staff Member | Role in the project (e.g., co-investigator, research coordinator, statistician, etc.) | Registered with LACDMH HR to be assigned under volunteer status | Will interact with study participants or have access to private identifiable data | Involved in the Informed Consent Process | Completed IRB Required Training (e.g., CITI) | Has a Conflict of Interest or Vested Interest in the Study (Attach Clarification) | Has completed HIPAA Training | Is a Part-Time or Full-Time Faculty Member of a College or University (enter which institution) | Submitted Evidence of Qualifications (PI only) |
| Enter text. |[ ]  Principal Investigator |[ ] [ ] [ ] [ ] [ ] [ ]  Enter text. | [ ]   |
| Enter text. |[ ]  Enter text. |[ ] [ ] [ ] [ ] [ ] [ ]   |  |
| Enter text.  |[ ]  Enter text. |[ ] [ ] [ ] [ ] [ ] [ ]   |  |
| Enter text.  |[ ]  Enter text. |[ ] [ ] [ ] [ ] [ ] [ ]   |  |
| Enter text.  |[ ]  Enter text. |[ ] [ ] [ ] [ ] [ ] [ ]   |  |
| Enter text.  |[ ]  Enter text. |[ ] [ ] [ ] [ ] [ ] [ ]   |  |
| Enter text.  |[ ]  Enter text. |[ ] [ ] [ ] [ ] [ ] [ ]   |  |
| Enter text.  |[ ]  Enter text. |[ ] [ ] [ ] [ ] [ ] [ ]   |  |
| Enter text.  |[ ]  Enter text. |[ ] [ ] [ ] [ ] [ ] [ ]   |  |
| Enter text.  |[ ]  Enter text. |[ ] [ ] [ ] [ ] [ ] [ ]   |  |

|  |
| --- |
| 1. Attestation
 |
| [ ]  I certify that the information I provided on this form is correct and complete. |
| This form was completed by Click here to enter text. | Date: Click here to enter a date. |
| 1. Principal Investigator Assurance (included in Instructions, page 7)
 |
| [ ]  I agree to follow all applicable policies and procedures of the LACDMH, federal, state, and local laws and guidelines regarding the protection of human subjects in research, as well as professional practice standards and generally accepted, good research practice for investigators (see Instructions for details).[ ]  I verify that the information provided in this HSRC Application for Research is accurate and complete.[ ]  I agree that the information collected in this HSRC Application for Research will only be used for this specific study. [ ]  I agree that if any of the information gathered during the course of this study is to be used for *future* research studies, it will require specific approval from LACDMH HSRC. |
| Print Name: Click here to enter text. | Date: Click here to enter a date. |
| Signature: Digital Image or Physical Signature Only.  |

|  |
| --- |
| 1. Program Manager Approval

(Required for INITIAL Submissions Only) |
| [ ]  I have reviewed this application and all documents associated with this project. I have determined that all departmental requirements are met and that the investigators have adequate resources to conduct the project in terms of time, facilities, staff, access to a subject population, and resources. I intend to support the project with the necessary resources.[ ]  All research staff on site at LACDMH directly-operated clinics is required to register as volunteers with the LACDMH Human Resources Bureau prior to beginning any research activity. I am responsible for ensuring appropriate supervision, per DMH Policy 600.11.[ ]  I certify that I have reviewed the Conflict of Interest Policy, County Policy 608.02. This policy states, “No employee is permitted to accept any gifts or other considerations from any person, firm or corporation other than the County for the performance of an act that the employee would be required or expected to render in the regular course of their County employment.”Program/Clinic Site (including Service Area): Click here to enter text. |
| Print Name: Click here to enter text. | Date: Click here to enter a date. |
| Signature: Digital Image or Physical Signature Only. |
| 1. DMH Deputy Director Approval

(Required for INITIAL Submissions Only) |
| [ ]  I have reviewed this application and documents associated with this project. I have determined that the investigators have adequate resources to conduct the project in terms of time, facilities, staff, access to a subject population, and resources. I intend to support the project with the necessary resources. |
| Print Name: Click here to enter text.Title: Click here to enter text. | Date: Click here to enter a date. |
| Signature: Digital Image or Physical Signature Only.  |
| If you have additional sites, complete the Additional Site Form, page 23 of this application. Attach it to the application when submitting to the appropriate individuals. Submit this form to the HSRC only after the signatures are obtained.[ ]  Additional Program Manager and DMH Deputy Director Approval(s) attached. |

**PART II - HUMAN SUBJECTS RESEARCH COMMITTEE**

**PROTOCOL SUMMARY**

|  |
| --- |
| Not all sections of the protocol summary may apply. Please complete only pertinent sections.For all sections that do not apply, please indicate “Not Applicable” or check N/A. |
|  |
| 1. Study Purpose and Rationale

*Describe the background, objective, purpose, intent, and scientific aims of the human research in a short paragraph. State the hypothesis to be tested and how the information collected will be utilized. Include pertinent background description with references that are related to the need for this study.* |
| Click here to enter text. |
| 1. Study Design and Statistical Procedures

*Describe the procedures in sufficient detail so that a reviewer who is not familiar with them can comprehend what is to be done and can evaluate any risks. Delineate procedures that are already being performed for diagnostic or treatment purposes from those that are being done for research, i.e., clearly identify those procedures that would be occurring whether or not the individual was participating in this research. Describe how the data will be analyzed.* |
| Click here to enter text. |
| 1. Sites

*List the sites, including address, where this project will be conducted. When applicable, list: 1) institutions or sites (both directly-operated and contracted facilities) where research procedures will be performed, and 2) the location(s) where potential participants may be identified and recruited.* |
| Click here to enter text. |
| 1. Study Participants

*Indicate the total number of participants to be recruited or records to be reviewed and if applicable at each site. If applicable, distinguish between the number of participants who are expected to be screened, enrolled (consent obtained), randomized, have completed the research-related procedures, and between sub-groups (health volunteers vs. treatment cohort).*Is there an intervention or interaction with a living person that would not otherwise be occurring, but for research purposes? [ ]  Yes [ ]  No |
| Click here to enter text. |

|  |  |
| --- | --- |
| 1. Vulnerable Populations
 | [ ]  N/A |
| *Please indicate if individuals from the following populations or with the following conditions are targeted for recruitment and/or enrollment.* |
| [ ]  Children/Adolescents[ ]  Pregnant Women[ ]  Older Adults[ ]  LACDMH or other County Employees | [ ]  Mental Illness[ ]  Disability[ ]  Homeless[ ]  Other: Click here to enter text. |
| 1. Screening and Eligibility Criteria
 | [ ]  N/A |
| *Give detailed inclusion and exclusion criteria and number of potential participants to be enrolled based on the statistical description and any other considerations. Describe how participants will be screened for eligibility.* |
| Click here to enter text. |
| 1. Recruitment Method
 | [ ]  N/A |
| *Describe in detail how participants will be recruited including type (e.g., newspaper advertisements, posters, flyers, staff referrals) and location (e.g., private practices, clinics, directly-operated or contracted facilities). Attach a copy of each written advertisement and the script for each recruitment media or method that is verbal (e.g., video, telephone script). Identify who will be conducting the recruitment and if this person is affiliated with LACDMH.*Will participants be compensated for their participation? [ ]  Yes [ ]  No*Please describe when, where and how the compensation will be exchanged.*Click here to enter text.Will the acknowledgment of receipt of compensation contain any identifiable information? [ ]  Yes [ ]  No*If yes, how will the information be safeguarded?*Click here to enter text.Will study participants be communicating with the investigator via telephone? [ ]  Yes [ ]  No*Describe your protocol for leaving voice messages for the participants.*Click here to enter text.Will participants be communicating with the investigator via e-mail? [ ]  Yes [ ]  No*Describe your protocol for exchanging e-mail messages.*Click here to enter text.[ ]  Study Instrument(s) attached[ ]  Outreach media attached (i.e., flyers, e-mails, advertisements). Indicate where you will be recruiting research participants.*Provide the information for each checked box below, including facility name, address, and contact person for each clinic.*[ ]  DMH Directly-Operated Facilities: Click here to enter text.[ ]  DMH LE Contracted Providers: Click here to enter text. [ ]  Other: Click here to enter text. |
| H. Informed Consent Process [ ]  N/A*Describe how consent will be obtained, including by whom (i.e., principal investigator, co-investigator, study coordinator), when, and by what method (e.g., in-person, verbally by telephone). Be sure to describe the means of communication if non-English speaking, illiterate, or if other vulnerable persons will be included among study participants. Also, if necessary, describe any visual aids or devices that may be used to help explain a complicated procedure or process.*[ ]  An Informed Consent Document describing the research WILL be provided to the participant or the participant’s legally authorized representative for signature.[ ]  An Informed Consent Document will be provided; however, NO signature will be obtained. Complete a Waiver of Documentation of Informed Consent in Part III, Section A.[ ] An information sheet describing the research WILL be provided to the participant or the participant’s legally authorized representative.[ ] Participants WILL NOT receive an information sheet.[ ]  No Consent will be obtained. Complete a Waiver of Informed Consent process in Part III, Section A.*For all requests for a waiver of informed consent or alteration of the consent process, the following criteria must be met:*1. *The research involves no more than minimal risk to the participants;*
2. *The waiver or alteration will NOT adversely affect the rights and welfare of the participants;*
3. *The research could NOT practicably be carried out without the waiver or alteration; and,*
4. *Whenever appropriate, the participants will be provided with additional pertinent information after their participation.*

*For all requests for a waiver of documentation of informed consent, the following criteria must be met:*1. *The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research and the participant’s wishes will govern or*
2. *That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.*

[ ]  Consent document(s) and/or information sheet(s) attached |
| Click here to enter text. |
| I. Additional Informed Consent Provisions | [ ]  N/A |
| [ ]  Children/Adolescents*Describe whether child participants may be expected to attain legal age to consent to the procedures of the research prior to the completion of their participation in the research (including storage of samples). If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Describe the timing of this process, and what will occur if consent is not obtained from the participants.**Parental permission will be obtained from:*[ ]  *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*[ ]  *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*[ ]  *Permission will be obtained from individuals other than parents. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care in the text box below.*[ ]  *No parental permission will be obtained. Justification is to be provided in the text box below.**Assent from the children/adolescents will be obtained from:*[ ]  *All of the children/adolescents.*[ ]  *Some of the children/adolescents. Please indicate which children/adolescents will be required to assent in the text box below.*[ ]  *None of the children/adolescents. Justification is to be provided in the text box below.*[ ]  Non-English Speaking Study Participants*Indicate what language(s) other than English are understood by prospective participants or representatives. List any investigator(s) and/or staff who are fluent in the language(s) of the prospective participants. If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Describe how translation services will occur during the participant recruitment processes, during the consent processes, and throughout the study. Describe how research staff will respond to emergency questions or problems from non-English speaking participants.**Please note that an oral translator is not sufficient for the enrollment of individuals who do not speak English. The English, HSRC approved consent document must be translated into another language and submitted for HSRC approval before a non-English speaking participant is enrolled. Accuracy of the translation must be certified (or attested). Attach an Oath of Confidentiality Agreement if translation services are being used.* |
| Click here to enter text. |
| 1. Potential Risks

*Describe risks including data on risks that have been encountered in past studies. That is, if the occurrence of a certain adverse event was 20%, include those data in this description. Please include steps that will be taken to minimize the risks or harms to protect the welfare of participants.*[ ]  No More than Minimal Risk[ ]  Minimal Risk[ ]  Greater than Minimal Risk |
| Click here to enter text. |
| 1. Potential Benefits

*This description should be based on accrued data from related studies that have been completed. Anticipated benefits of this study may include to society, knowledge, and/or direct benefit to the participants. Please note that compensation cannot be a potential benefit for participating in the study.* |
| Click here to enter text. |
| 1. Alternatives

*Describe alternative therapies by providing data to support their efficacy or lack of efficacy. An important alternative is also not to participate in this research.* |
| Click here to enter text. |

|  |
| --- |
| 1. Study Procedures

*Describe all research procedures (e.g., questionnaires, record reviews, surveys, medical exams) and when they will be performed (e.g., baseline, initial visit, follow-up visits). Describe any survey/interview questions that might be sensitive in nature. Submit a copy of the survey, questionnaire, and interview questions. List standardized measures used.* |
| Click here to enter text. |
| 1. Confidentiality of Study Data

*Describe how confidentiality of study data will be maintained (if it is to be maintained) locally, and during transmission to another site, if applicable. Include a clear description of how data will be stored, specifically indicating whether data will contain direct or indirect identifiers. Describe protections related to accessing the study data, whether in an electronic or paper form.**Please note that “de-identified” means that all identifiers have been removed and no one (research team or others) can identify from whom the data or sample was collected. “Coded” means that the data/specimens are labeled with a code number, and there is a link between the respondent/donor and the data/specimen, i.e., someone can identify from whom the data/sample was collected if they have the link to the code. For any coded data/samples, indicate who, if anyone on the research team has access to the identifiable data.**If personal identifiers are to be collected, please indicate in the text box below which identifiers will be obtained (i.e., names, dates of birth, addresses, telephone numbers, social security numbers, medical records, license numbers, IP addresses, photos, images, unique identifiers and/or etc.). See a list of 18 HIPAA Identifiers in the Instructions, page 4.*Will identifiable private information be obtained for this research in any form directly or indirectly associated with a living individual? [ ]  Yes [ ]  No |
| Click here to enter text. |

**PART III - HUMAN SUBJECTS RESEARCH COMMITTEE**

**SUPPLEMENTAL DOCUMENTS AND ATTACHMENTS**

|  |
| --- |
| Complete and submit only if the sections are applicable.For all sections that do not apply, please indicate “Not Applicable” or check N/A. |
|  |
| 1. Waiver of Consent Documentation
 | [ ]  N/A |
| *Respond to ALL questions 1 through 6. Answers to questions 2 and 3 must be “No,” OR answers to questions 4 and 5 must be “Yes.”**The participant should be asked whether he/she wants documentation linking the participant with the research. The participant’s choice takes precedence.* |
| 1. Is the research subject to FDA regulations (i.e., involves use of a food, drug, biological device)?
 | [ ]  Yes [ ]  No |
| 1. Does the research present greater than minimal risk?
 | [ ]  Yes [ ]  No |
| 1. Does the research involve procedures for which written consent is normally required outside the research context?
 | [ ]  Yes [ ]  No |
| 1. Would the only record linking the participant and the research be the consent document?
 | [ ]  Yes [ ]  No |
| 1. Would the principal risk to the participant be potential harm resulting from a breach in confidentiality?
 | [ ]  Yes [ ]  No |
| 1. Explain why a Waiver of Consent Documentation is necessary to conduct the research (provide a detailed description in the text box below).
 |
| Click here to enter text. |

|  |  |
| --- | --- |
| 1. Waiver or Alteration of Consent Process
 | [ ]  N/A |
| *Respond to questions 1 through 5 as applicable, providing a detailed description. If the research involves a product regulated by the FDA or the results of the research may be submitted to the FDA as part of a marketing application, consent cannot be waived.* |
| 1. Is the research subject to the approval of state or local government officials, and designed to study public benefit, service programs, and procedures for obtaining benefits under those programs, changes in or alternatives to those programs or procedures, or changes in methods or levels of payment for benefits or services under those programs?
 | [ ]  Yes [ ]  No |
| Click here to enter text. |
| 2. Explain why the research could not practicably be carried out without the Waiver or Alteration. |
| Click here to enter text. |
| *If the answer to question 1 above is “No,” complete question(s) 3, 4, and 5, to request a Waiver or Alteration.*1. Explain how the research involves no more than minimal risk.
 |
| Click here to enter text. |
| 1. Explain why the Waiver or Alteration will not adversely affect the rights or welfare of the participants.
 |
| Click here to enter text. |
| 1. Will the participants be provided with additional relevant information after participation? Explain why or why not.
 | [ ]  Yes [ ]  No |
| Click here to enter text. |
| 1. Waiver of HIPAA Research Authorization
 | [ ]  N/A |
| *Use this form to request a waiver or alteration of HIPAA authorization to access, use, or disclose Protected Health Information (PHI) for the proposed research. The Privacy Rule allows waivers (or alterations) of authorization under certain conditions.* |
| 1. Select the type of waiver/alteration requested.
 |  |
| * 1. Partial Waiver (recruitment purposes)
 | [ ]  Yes [ ]  No |
| 1. Full Waiver (entire research study)
 | [ ]  Yes [ ]  No |
| 1. Alteration (written documents)
 | [ ]  Yes [ ]  No |

|  |
| --- |
| 1. Provide details regarding PHI involved in the research (e.g., medical record numbers, diagnoses, test results, etc.). Describe how the PHI was accessed for the research, including the source.
 |
| Click here to enter text. |
| 1. Describe the information that will be recorded.
 |
| Click here to enter text. |
| 1. Explain how access to and/or use of the PHI is necessary to conduct the research.
 |
| Click here to enter text. |
| 1. Explain how the PHI is the minimum necessary to achieve goals of the research.
 |
| Click here to enter text. |
| 1. Explain how the access, use, or disclosure of PHI presents no more than a minimal risk to the privacy of the individual.
 |
| Click here to enter text. |
| 1. Describe your plan to protect the identifiers (or links to identifiable data) associated with the PHI from improper use and disclosure, including where PHI will be stored, what security measures will be applied, and who will have access to the information. Describe the safeguards for electronic and/or hard copy records.
 |
| Click here to enter text. |
| 1. Will identifiers (or links to identifiable data) be destroyed?
 | [ ]  Yes [ ]  No [ ]  N/A |
| 1. If yes, describe the plan to destroy the identifiers at the earliest opportunity. Include when and how identifiers will be destroyed.
2. If no, provide the legal, health, or research justification for retaining the identifiers. Legal justification should include a brief description/citation of the legal requirement.
3. If N/A, investigators will not record identifiers or create links or codes to connect the data.
 |
| Click here to enter text. |
| 1. Describe why a waiver or alteration (instead of written authorization) is needed to conduct the research.
 |
| Click here to enter text. |

**EXHIBIT A**

**Privacy Protections**

|  |
| --- |
| *Please read the Data Privacy and Security Guidelines in the Instructions, starting on page 4 before completing Exhibit A.* |
| Privacy Protections*1. Describe how the participant’s privacy will be protected, and the limits to protection. Privacy protection may be summarized as safeguarding an individual’s expectation that the information they offer will be held in confidence. Protections should cover the following as applicable: research settings, screening activities, HIPAA provisions, forums such as focus groups where private information may be shared, transporting PHI by vehicle or on foot, and recordings of research activities. Limitations such as compelled disclosure and mandatory reporting should also be described.**Describe how long the PHI will be stored and the methods of destruction that will be used when discarding both electronic and paper documents with PHI.**Describe the required procedure to report unauthorized access, use or disclosure of PHI or confidential data.*[ ]  The project includes audio recordings. List the make and model, as well as the plan to maintain privacy and security, in the text box below.[ ]  The project includes video recordings. List the make and model, as well as the plan to maintain privacy and security, in the text box below.[ ]  The project includes external transcription services. An Oath of Confidentiality Agreement is attached. |
| Click here to enter text. |
| 2. Please select all the data elements/data fields that will be collected during the project. |
|

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]   | Names | [ ]   | Medical Record Numbers |
| [ ]   | All geographical subdivisions smaller than a State (street address, city, zip) | [ ]   | Health Plan Beneficiary Numbers |
| [ ]   | All elements of dates (except year) for dates directly related to an individual (birth date, admission date, discharge date) | [ ]   | Biometric identifiers (finger and voice prints) |
| [ ]   | Telephone Numbers | [ ]   | Full face unique identifying number, characteristic, or code |
| [ ]   | Fax Numbers | [ ]   | Device identifiers and serial numbers |
| [ ]   | Electronic Mail Addresses | [ ]  | Account Numbers |
| [ ]   | Social Security Numbers | [ ]   | Internet Protocol (IP) address numbers |
| [ ]   | Certificate/License Numbers | [ ]   | Web Universal Resource Locators (URLs) |
| [ ]   | Vehicle identifiers and serial numbers (license plate numbers) | [ ]  | Any other unique identifying number, characteristic, or codeOther: Click here to enter text.  |

 |
| 3. How will the data be provided/collected? *Provide the contact information for each checked box below, including contact person’s name, email, and telephone.* |
| [ ]  DMH Directly-Operated Clinics: Click here to enter text.[ ]  DMH Headquarters/DMH Executives and CIOB: Click here to enter text.[ ]  DMH LE Contracted Providers: Click here to enter text.[ ]  Directly from Clients: Click here to enter text. |
| 4. Will you be conducting direct interviews with the participants? [ ]  Yes [ ]  No*If yes, please indicate all applicable categories that the interviewees will be selected from.* |
| [ ]  DMH Employees[ ]  DMH LE Contracted Provider Employees[ ]  DMH Clients[ ]  DMH LE Contracted Provider Clients [ ]  Public | [ ]  Children/Adolescents[ ]  Pregnant Women[ ]  Older Adults[ ]  Adults[ ]  Homeless |
| 5. Describe the recruitment process and all the methods of communication that will be used to connect or contact participants during the research (e.g. flyer, pamphlet, email, mail, telephone, voicemail). Explain how the communication will be secured and protected from unauthorized access. |
| Click here to enter text. |
| 6. Indicate where you will be recruiting research participants. *Provide the information for each checked box below, including facility name, address, and contact person for each clinic* |
| [ ]  DMH Directly-Operated Facilities: Click here to enter text.[ ]  DMH LE Contracted Providers: Click here to enter text.[ ]  Other: Click here to enter text. |
| 7. Indicate where you will be interviewing research participants. *Provide the information for each checked box below, including facility name, address, and contact person for each clinic.* |
| [ ]  DMH Directly-Operated Facilities: Click here to enter text.[ ]  DMH LE Contracted Providers: Click here to enter text.[ ]  Other: (e.g. home, clinic, in the field) Click here to enter text. |
| 8. Will participants be compensated for their participation? [ ]  Yes [ ]  No*Please describe when, where, and how the compensation will be exchanged.* |
| Click here to enter text. |
| 9. Will the acknowledgment of receipt of compensation contain any identifiable information? [ ]  Yes [ ]  No*If yes, how will the information be safeguarded?* |
| Click here to enter text. |
| 10. Will participants be communicating with the investigator via telephone? [ ]  Yes [ ]  No*Describe your protocol for leaving voice messages for the participants.* |
| Click here to enter text. |
| 11. Will participants be communicating with the investigator via e-mail? [ ]  Yes [ ]  NoDescribe your protocol for exchanging e-mail messages. |
| Click here to enter text. |
| 12. What methods of transportation will be used when transporting paper documents that contain PHI or confidential data? (e.g. locked box, stored in locked trunk of a vehicle) |
| Click here to enter text. |
| 13. How long will the PHI/Confidential data be stored?*Describe the security protocol that will be in place when data is at rest to secure the information from unauthorized access and for how long? (i.e., 2 years, June 2020)* |
| Click here to enter text. |
| 14. What methods of destructions will be used when discarding both electronic and paper documents with PHI or confidential data? |
| Click here to enter text. |
| 15. Will any data (including de-identified data) be accessed, shared or exchanged with anyone other than the PI and team (e.g., Transcription Service)? If so, please describe the PI’s relationship with the person(s) or entity (Contract – Business Associate Agreement – Other Arrangement). |
| Click here to enter text. |
| 16. Describe your Incident Response and Escalation Procedures for reporting unauthorized access, use or disclosure of PHI or confidential data. |
| Click here to enter text. |

|  |
| --- |
| NO RESEARCH ACTIVITY CAN BEGIN BEFORE FINAL APPROVAL FROM THE HSRC |
| DMH Privacy Officer Approval |
| [ ]  The DMH Privacy Officer has reviewed the plan for protecting client data, and has determined the plan meets or exceeds the minimum privacy protection requirements, with the exception of the following:Click here to enter text. |
| Print Name: Click here to enter text. | Date: Click here to enter a date. |
| Signature: Digital Image or Physical Signature Only.  |

**EXHIBIT B**

**Information Technology Safeguarding**

|  |
| --- |
| *Please read the Data Privacy and Security Guidelines in the Instructions, starting on page 4 before completing Exhibit B.* |
| Protection of Information and Safeguarding the Infrastructure |
| 1. Principal Investigator:
 | Click here to enter text. |
| 1. Research Study Title:
 | Click here to enter text. |
| 1. Contact information for the individual filling out the form:
 | Name: Click here to enter text.Email: Click here to enter text.Telephone: Click here to enter text. |
| 1. How will the data be provided/collected?

*Provide the contact information for each checked box below, including contact person’s name, email, and telephone.* |
| [ ]  DMH Directly-Operated Clinics: Click here to enter text.[ ]  DMH Headquarters/DMH Executives and CIOB: Click here to enter text.[ ]  DMH LE Contracted Providers: Click here to enter text.[ ]  Directly from Clients: Click here to enter text. |
| 1. Will you be conducting direct interviews with the participants? [ ]  Yes [ ]  No

*If yes, please indicate all applicable categories that the interviewees will be selected from.* |
| [ ]  DMH Employees[ ]  DMH LE Contracted Provider Employees[ ]  DMH Clients[ ]  DMH LE Contracted Provider Clients [ ]  Public | [ ]  Children/Adolescents[ ]  Pregnant Women[ ]  Older Adults[ ]  Adults[ ]  Homeless |
| 1. Describe the recruitment process and all the methods of communication that will be used to connect or contact participants during the research (e.g. flyer, pamphlet, email, mail, telephone, voicemail). Explain how the communication will be secured and protected from unauthorized access.
 |
| Click here to enter text. |
| 1. Indicate where you will be recruiting research participants.

*Provide the information for each checked box below, including facility name, address, and contact person for each clinic* |
| [ ]  DMH Directly-Operated Facilities: Click here to enter text.[ ]  DMH LE Contracted Providers: Click here to enter text.[ ]  Other: Click here to enter text. |
| 1. Indicate where you will be interviewing research participants.

*Provide the information for each checked box below, including facility name, address, and contact person for each clinic.* |
| [ ]  DMH Directly-Operated Facilities: Click here to enter text.[ ]  DMH LE Contracted Providers: Click here to enter text.[ ]  Other: Click here to enter text. |
| 1. Will participants be compensated for their participation? [ ]  Yes [ ]  No

*Please describe when, where, and how the compensation will be exchanged.* |
| Click here to enter text. |
| 1. Will the acknowledgment of receipt of compensation contain any identifiable information [ ]  Yes [ ]  No

*If yes, how will the information be safeguarded?* |
| Click here to enter text. |
| 1. Will participants be communicating with the investigator via telephone? [ ]  Yes [ ]  No

*Describe your protocol for leaving voice messages for the participants.* |
| Click here to enter text. |
| 1. Will participants be communicating with the investigator via e-mail? [ ]  Yes [ ]  No

Describe your protocol for exchanging e-mail messages. |
| Click here to enter text. |
| 1. Please select all the data elements/data fields that will be collected during the project.
 |
|

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]   | Names | [ ]   | Medical Record Numbers |
| [ ]   | All geographical subdivisions smaller than a State (street address, city, zip) | [ ]   | Health Plan Beneficiary Numbers |
| [ ]   | All elements of dates (except year) for dates directly related to an individual (birth date, admission date, discharge date) | [ ]   | Biometric identifiers (finger and voice prints) |
| [ ]   | Telephone Numbers | [ ]   | Full face unique identifying number, characteristic, or code |
| [ ]   | Fax Numbers | [ ]   | Device identifiers and serial numbers |
| [ ]   | Electronic Mail Addresses | [ ]  | Account Numbers |
| [ ]   | Social Security Numbers | [ ]   | Internet Protocol (IP) address numbers |
| [ ]   | Certificate/License Numbers | [ ]   | Web Universal Resource Locators (URLs) |
| [ ]   | Vehicle identifiers and serial numbers (license plate numbers) | [ ]   | Any other unique identifying number, characteristic, or codeOther: Click here to enter text. |

 |
| 1. Describe in detail the data’s flow from collection to destruction.

*Thoroughly describe the workflow by explaining how the information will be protected from unauthorized access throughout every process and procedure.* |
| Click here to enter text. |
| 1. What methods of transportation will be used when transporting paper documents that contain PHI or confidential data?
 |
| Click here to enter text. |
| 1. Are you transmitting data electronically? [ ]  Yes [ ]  No

*Describe the security protocol that will be in place during transmission that will secure the information from unauthorized access.* |
| Click here to enter text. |
| 1. How long will the PHI/Confidential data be stored?

*Describe the security protocol that will be in place when data is at rest to secure the information from unauthorized access and for how long? (i.e., 2 years, June 2020)* |
| Click here to enter text. |
| 1. What methods of destructions will be used when discarding both electronic and paper documents with PHI or confidential data?
 |
| Click here to enter text. |
| 1. If you are using an audio or video recording device, list the make/model of each device.
 |
| Click here to enter text. |
| 1. If you are uploading data (de-identified, PHI, or confidential data) to a website, list the URL.
 |
| Click here to enter text. |
| 1. Will any data (including de-identified data) be accessed, shared or exchanged with anyone other than the PI and team (e.g., Transcription Service)? If so, please describe the PI’s relationship with the person(s) or entity (Contract – Business Associate Agreement – Other Arrangement).
 |
| Click here to enter text. |
| 1. Describe your Incident Response and Escalation Procedures for reporting unauthorized access, use or disclosure of PHI or confidential data.
 |
| Click here to enter text. |

|  |
| --- |
| NO RESEARCH ACTIVITY CAN BEGIN BEFORE FINAL APPROVAL FROM THE HSRC LACDMH CIOB Information Security Officer or Designee Approval |
| [ ]  LACDMH CIOB Information Security Officer has reviewed the proposed study, and finds the data plan described consistent with DMH policy and meets or exceeds standards for protection of sensitive data/PHI, with the exception of the following:Click here to enter text. |
| Print Name: Click here to enter text. | Date: Click here to enter a date. |
| Signature: Digital Image or Physical Signature Only. |

|  |
| --- |
| 1. Are you requesting any electronic data from LACDMH Clinical Informatics? [ ]  Yes [ ]  No

*If yes, describe in detail the resources requested from LACDMH Clinical Informatics.* |
| Click here to enter text. |
| LACDMH Chief, Clinical Informatics Approval (if Applicable) |
| [ ]  LACDMH Clinical Informatics has reviewed the proposed project as described in this application and will support the project with the necessary resources (only required if requesting data from Clinical Informatics). |
| Print Name: Click here to enter text. | Date: Click here to enter a date. |
| Signature: Digital Image or Physical Signature Only. |
| 1. Are you requesting any electronic data from LACDMH CIOB? [ ]  Yes [ ]  No

*If yes, describe in detail the resources requested from LACDMH CIOB.* |
| Click here to enter text. |
| LACDMH CIOB Chief Information Officer Approval (if Applicable) |
| [ ]  LACDMH CIOB Chief Information Officer has reviewed the proposed project as described in this application and will support the project with the necessary resources (only required if electronic data is requested). |
| Print Name: Click here to enter text. | Date: Click here to enter a date. |
| Signature: Digital Image or Physical Signature Only. |

|  |
| --- |
| USE THIS FORM FOR ANY ADDITIONAL SITES |
|  |
| Additional Program Manager and DMH Deputy Director Approval  |
| Program Manager Approval |
| Name of Site: Click here to enter text.Site Address: Click here to enter text.[ ]  I have reviewed this application and all documents associated with this project. I have determined that all departmental requirements are met and that the investigators have adequate resources to conduct the project in terms of time, facilities, staff, access to a subject population, and resources. I intend to support the project with the necessary resources.[ ]  All research staff on site at LACDMH directly-operated clinics is required to register as volunteers with LACDMH Human Resources prior to beginning any research activity. I am responsible for ensuring appropriate supervision, per DMH Policy 600.11.[ ]  I certify that I have reviewed the Conflict of Interest Policy, County Policy 608.02. This policy states, “No employee is permitted to accept any gifts or other considerations from any person, firm or corporation other than the County for the performance of an act that the employee would be required or expected to render in the regular course of their County employment.” |
| Print Name: Click here to enter text. | Date: Click here to enter a date. |
| Signature: Digital Image or Physical Signature Only. |
| DMH Deputy Director Approval |
| [ ]  I have reviewed this application and documents associated with this project. I have determined that the investigators have adequate resources to conduct the project in terms of time, facilities, staff, access to a subject population, and resources. I intend to support the project with the necessary resources. |
| Print Name: Click here to enter text. | Date: Click here to enter a date. |
| Signature: Digital Image or Physical Signature Only.  |