 Human Subjects Research Committee

 hsrc@dmh.lacounty.gov

**HUMAN SUBJECTS RESEARCH COMMITTEE**

**APPLICATION FOR CONTINUING REVIEW FORM (CRF)**

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| **PART A: INFORMATION** |
| Protocol Title: | Click here to enter text. |
| Protocol Number: | **PLEASE ENTER PROTOCOL NUMBER** |
| Principal Investigator (PI): | Click here to enter text.  |
| Date of Submission: | Click here to enter a date. |

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| PART B: PRINCIPAL INVESTIGATOR ASSURANCE & ATTESTATIONS |
| I, the Principal Investigator, agree to follow all applicable policies and procedures of the Los Angeles County Department of Mental Health (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 guidelines for investigators including, but not limited to, the following: |
| **B1: GENERAL ATTESTATION**1. Initiate the research only after Human Subjects Research Committee (HSRC) approval of the Application for Research has been received.
2. Ensure that all non-DMH researchers conducting research at DMH directly-operated sites register with LACDMH Human Resources Bureau as volunteers.
3. Perform the research as approved by the HSRC, utilizing appropriately trained and qualified personnel with adequate resources.
4. Obtain and document (unless waived) informed consent and HIPAA research authorization from human subjects (or their legally authorized representatives) prior to their involvement in the research using the HSRC-approved consent form(s) and proposed recruitment process.
5. Promptly report to the HSRC any events that represent unanticipated problems involving risks to subjects or others, and/or significant new findings that may relate to the subjects willingness to continue to participate.
6. Inform the HSRC of any proposed changes in the research or informed consent process before changes are implemented, and agree that no changes will be made until approved by the HSRC (except where necessary to eliminate apparent immediate hazards to participants).
7. Complete and submit an Application for Continuing Review 45 days prior to the expiration date of the previous HSRC approval period at one-year intervals and/or as determined by the HSRC to be appropriate to the degree of risk (but not less than once per year) to avoid expiration of HSRC approval and cessation of research activities.
8. Complete and submit an Application for Continuing Review (including Section 11 - Final Study

 Review) when all research activities have ended.1. Maintain research-related records in a manner that supports the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants.
2. Retain research-related records for audit for a period of at least six (6) years after the research has ended (or longer, according to sponsor or publication requirements).
3. Submit manuscripts to the LACDMH HSRC for review prior to submission for publication to ensure that PHI is not included.
4. Provide copies of all publications resulting from the research project.
5. Maintain current IRB renewals.
6. Adhere to County Policy 608.02, which 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.”
7. Inform all co-investigators, research staff, employees, and LACDMH staff assisting in the conduct of the research of their obligations in meeting this Assurance.
8. Complete a HIPAA Training.
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| **B2: DATA SECURITY ATTESTATION**1. Understand that project approval applies only to the protocol processes documented in the HSRC Application including the Privacy Protections and Protection of Information and Safeguarding the Infrastructure sections.
2. Agree that any changes in the scope, methodology or in the configuration of systems and tools to those previously approved must be reviewed and approved by LACDMH HSRC prior to implementation.
3. Report changes or be subject to possible suspension of all activities or cancelation of the project.
4. Acknowledge that LACDMH may conduct audits to validate my full compliance with the LACDMH HSRC Application “Assurance” section.
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| Print Name: Click here to enter text. | Date: Click here to enter a date. |
| Signature: Digital Image or Physical Signature Only.  |

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| PART C: APPLICATION FOR CONTINUING REVIEW\* |
| Instructions: Please check the necessary boxes and provide a description as applicable. Enter “N/A” for questions that do not apply. Do not leave any blanks.\*An HSRC Continuing Review Approval is no longer necessary when: (1) the principal investigator no longer collects data about the subjects of the research through intervention or interaction; (2) the principal investigator no longer collects or maintains identifiable private information about the subjects of the research. Any remaining data stored must be fully de-identified (e.g., all 18 HIPAA identifiers are removed, per DMH policy 500.04). |
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| C1. Principal Investigator Information |
| Has the principal investigator’s information changed since the last HSRC review?Yes [ ]  No [ ] If *yes*, please enter any new information below: |
| E-mail: Click here to enter text.Phone: Click here to enter text.Full Mailing Address: Click here to enter text.Name of Institution: Click here to enter text. |  |
| Department: Click here to enter text. |
|  C2. DMH Co-investigator(s) and/or staffNote: DMH Co-Investigators and/or Staff are individuals who are employed by DMH and participate in the design, conduct, or reporting of human subjects’ research. At minimum, include individuals who recruit or consent participants or who collect study data. |
| Has the co-investigator’s information changed since the last HSRC review?Yes [ ]  No [ ] If *yes*, please enter any new information below:Co-Investigator: Click here to enter text.Title/Position: Click here to enter text.E-mail: Click here to enter text.Phone: Click here to enter text.Full Mailing Address: Click here to enter text.Research Role/Activities Performed: Click here to enter text. |  |
|  C3. Research SiteNote: Please complete the attached Additional Site Form for each research site added since the last HSRC review. |
| Has any research sites been added or dropped?Yes [ ]  No [ ] If *yes*, please specify: Click here to enter text. |
|  C4. Funding or Other Support |
| Have there been any changes in the funding status of the research?Yes [ ]  No [ ] If *yes*, please specify: Click here to enter text. |
|  C5. New LACDMH Resources Requested\*Note: Please indicate if there are any new DMH resources requested since the last HSRC review/approval. |
| Staff Time: Yes [ ]  No [ ] Clinic/Office Space: Yes [ ]  No [ ] Electronic Data Extraction: Yes [ ]  No [ ] Other: Click here to enter text.\* If any new LACDMH resources are being requested since the last HSRC review or if any current resources have changed since the last HSRC review, a Request For Amendment Form is also required.  |
|  C6. Research Status |
| Enrollment: [ ]  No research participants have been enrolled (or participant records, specimens, etc. obtained).[ ]  Research participants have been enrolled (or participant records, specimens, etc. obtained).Recruitment:[ ]  Recruitment is ongoing.[ ]  Recruitment has been completed [ ]  Participants have not completed research interventions.  [ ]  All participants have completed all research interventions. [ ]  Research remains active only for long-term follow-up (or re-contact) and data analysis. [ ]  Research remains active only for data analysis.IRB Status:[ ]  IRB renewals are current. |
|  C7. Research Progress |
| Summarize the progress of the research, including any preliminary findings.Click here to enter text.Summarize any HSRC approved amendments or changes made to the research since the last HSRC review (initial or continuing). Include the dates that the amendments were approved if any. If HSRC approval was not obtained prior to the changes, provide an explanation.Click here to enter text.Discuss significant new findings (e.g., affecting risks, benefits, or alternatives), if any, that could impact participants’ decision to continue in the research and how they have been or will be informed.Click here to enter text. |
|  C8. Number of ParticipantsNote: Participants are defined as individuals who agreed to participate (i.e. those who provided consent or whose records were accessed, etc.) even if they do not prove eligible or complete the study. Please indicate: |
| Total number of participants enrolled in the research to date:Click here to enter text.Number of participants enrolled since the last HSRC review (initial or continuing):Click here to enter text. |
|  C9. Risk Assessment |
| Since the last HSRC review (initial or continuing), did any problems involving risks to subjects or others or adverse events occur? If yes, please provide a thorough explanation as an attachment to this application.Yes [ ]  No [ ] Detail any change in the risks and potential benefits based on study results since the last HSRC review.Click here to enter text. |
|  C10. Participant Complaints & WithdrawalsNote: Do not include individuals whose participation was discontinued by the investigator or sponsor because of unanticipated problems, study completion, etc. |
| Have any participants made complaints about the research since the last HSRC review?Yes [ ]  No [ ] If *yes*, list and describe each complaint and any actions taken to resolve the complaint(s).Click here to enter text.Have any participants withdrawn from the research since the last HSRC review?Yes [ ]  No [ ] If *yes*, list and describe each withdrawal and any actions taken (e.g., changes to the research or consent process) in response to the withdrawal(s).Click here to enter text. |
| PART D: FINAL STUDY REVIEW |
| Note: *Complete ONLY if all research activity has concluded.*Summarize the results of the study, including any plans for scholarly/scientific presentations or publications.Click here to enter text.Do you plan to submit an article for publication?Yes [ ]  No [ ] If *yes*, please submit a copy of the abstract and manuscript to HSRC prior to publication. Investigators must provide copies of publications resulting from their HSRC approved research projects to HSRC as they become available (per the Application Instructions, page 1, #3)Click here to enter text. |

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| ADDITIONAL SITE FORM |
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| Instructions: Complete this form only if additional sites have been added since the last HSRC review, and obtain one form for each research site. This form is required for both LACDMH directly-operated sites, as well as legal entity contracted 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.  |