LOS ANGELES COUNTY DEPARTMENT OF MENTAL HEALTH

HUMAN SUBJECTS RESEARCH COMMITTEE (HSRC)

APPLICATION

Project Title: _____

Principal Investigator: _____

Date of Initial Submission: _____

Table of Contents/Checklist

PART I - APPLICATION INSTRUCTIONS

Does my research need HSRC review?

1. The Los Angeles County Department of Mental Health (LACDMH) Human Subjects Research Committee (HSRC) must review and approve all human subjects research projects involving LACDMH programs, staff and data. *Research activities cannot begin until HSRC approval is obtained.* This includes LACDMH directly-operated programs, and programs with LACDMH legal entity (LE) agreements. Directly-operated clinic program sites are operated and managed with LACDMH employed staff; LE contract providers are funded by LACDMH, but operated and managed by private organizations. Research that studies LACDMH LE contractors' staff is exempt from HSRC review.

2. Research that involves human subjects as defined by federal guidelines and LACDMH Mental Health Review Policy No. 1400.01, Section 2.2, requires HSRC review.

   Human Subjects: A living individual about whom an investigator (whether professional or student) conducting research obtains:

   a. data through intervention or interaction with the individual
   b. identifiable private information

   Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

3. The intent to develop or contribute to generalizable knowledge makes an activity research. Activities designed with intent to develop or contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize finding beyond a single individual or an internal program (e.g., publication), require HSRC review. Results do not have to be published or presented to qualify the activity as research.

   a. Publication of Research: The HSRC requires that investigators submit copies of all abstracts and manuscripts prior to publication. Investigators must also provide copies of publications resulting from their HSRC-approved research projects to the HSRC as they become available.

4. HSRC review is not needed if the investigation primarily involves quality assurance activities, including program evaluations solely for internal assessments and program evaluations assessing the success of established programs or processes to continuously improve the program quality or performance where it is not the intention to share the results.

5. Posting/Distribution of Recruitment Flyers: To post or distribute flyers in LACDMH contracted or directly-operated facilities, research studies must be approved by the HSRC.

What general criteria are necessary to apply for HSRC review?

1. The LACDMH HSRC approves research which fits closely with its Departmental service mission, ability to allocate necessary associated resources, and responsibility to minimize to the greatest extent possible any risks to LACDMH clients or LACDMH.
2. In accordance with LACDMH policy, all LACDMH services provided as part of research activities must fully meet Departmental clinical, programmatic, and fiscal requirements, including those related to practice parameters, policies and procedures, and medical necessity.
3. The LACDMH HSRC is not a federally registered IRB. LACDMH requires that investigators have IRB approval from their home institution's federally registered Institutional Review Board (IRB). These IRBs must include an association with a specific research institution located in Los Angeles County. Other IRBs may be considered on a case-by-case basis.

How do I apply for HSRC approval?

The HSRC process prioritizes applications based on the relevance of the research question to LACDMH's mission, any potential research risks, and the resources requested.

1. HSRC Application Process: The HSRC will only initiate its review process for applications which are complete. A complete application includes documentation of IRB approval from the investigator's home institution's registered IRB, required documents, supporting letters, and applicable forms. The HSRC will schedule a meeting, at which time the principal investigator (PI) must be available by phone to the HSRC. The HSRC will identify any specific issues pertaining to LACDMH policies, impact on services, consent, etc. The investigator must then resolve these issues before the application is approved.
2. Letter of Support Form: Investigators are to obtain one Letter of Support Form per site from each LACDMH program site's respective program head, district chief, and deputy director. Letter(s) of support are required for both LACDMH directly-operated sites, as well as LE contracted sites. Signatures indicate respective signators' intent to support the research project with the necessary resources. Attach all applicable letter(s) with signatures in this section. For LE contractor sites, program head signator must have authority equivalent to a program head/clinic manager or above, and signatures from the district chief and deputy director responsible for overseeing their contracts are required. Investigators should anticipate that individuals who are responsible for programs may have other questions, or may request additional information before granting research approval.
3. Privacy Assessment Form: All investigators are required to complete Section 4 – Privacy Assessment Form.
4. Electronic Data Request/CIOB Assessment Form: All investigators are required to complete Section 5 Electronic Data Request/CIOB Assessment. See Data Privacy and Security Guidelines on page 4 for further information.
5. Volunteer Registration: All non-DMH research staff and investigators whose work will involve a physical presence in any directly-operated LACDMH clinic for recruitment, screening, study measures, etc., are required to register as a DMH volunteer with LACDMH Human Resources, and identify a DMH employee as a volunteer supervisor for the research project site.

6. Application Submission: Send the completed application, including the unsigned completed Privacy Assessment Form and Electronic Data Request/CIOB Assessment Form to hsrc@dmh.lacounty.gov. We will review for completeness and will forward it to the DMH Privacy Officer and the CIOB Security Officer. You will be contacted if additional information is needed.
7. Responding to Initial Review/Time Limit: To process the application in a timely manner, the investigator should respond as quickly as possible to any questions or suggested revisions during the initial review of the application. Applications should be completed within six (6) months of initial submission; e.g., Electronic Data Request/CIOB Assessment Form, Privacy Assessment Form and signed Letter(s) of Support. After the six (6) month, a new updated application will be required to continue the review process.
8. Attachments: Complete and submit the following documents, as applicable.

- Consent Documents Form(s)
- Recruitment Material(s)
- Data Collection Summary
- HIPAA Research Authorization Form(s)
- Bio-sketch for PI
- IRB Documents (IRB Application and IRB Approval Letter)

HSRC Contact Information

Phone: (213) 639-6348
E-mail address: hsrc@dmh.lacounty.gov

DATA PRIVACY AND SECURITY GUIDELINES

(Please read carefully before completing Section 5 and Section 6)

What is de-identified data?

1. Data is considered de-identified if the Los Angeles County Department of Mental Health (LACDMH) Chief Information Office Bureau (CIOB) is providing and de-identifying data or none of the 18 HIPAA identifiers are collected. If LACDMH CIOB is not providing or de-identifying the data, appropriate security measures must be taken by the investigator. All data not de-identified by CIOB which may contain identifiers (coded or not coded) are treated as Protected Health Information (PHI). The investigator's research is required to be in compliance with federal HIPAA laws and LACDMH policy.

2. The 18 HIPAA Identifiers include:

1. Names	7. Social Security Numbers	13. Device identifiers and serial numbers
2. All geographical subdivisions smaller than a State (street address, city, zip code)	8. Medical Record Numbers	14. Web Universal Resource Locators (URLS)
3. All elements of dates (except year) for dates directly related to an individual (birth date, admission date, discharge date)	9. Health Plan Beneficiary Numbers	15. Internet Protocol (IP) address numbers
4. Phone Numbers	10. Account Numbers	16. Biometric identifiers (finger and voice prints)
5. Fax Numbers	11. Certificate/License Numbers	17. Full face unique identifying number, characteristic, or code
6. Electronic Mail Addresses	12. Vehicle identifiers and serial numbers (license plate numbers)	18. Any other unique identifying number, characteristic, or code

How do investigators demonstrate how they will ensure security of PHI?

LACDMH requires compliance with the "Health Information Technology for Economic and Clinical Health (HITECH)" Act. HITECH Act of 2009 defines PHI as "rendered, unusable, unreadable, or indecipherable" if the data is either encrypted or destroyed by approved technology or methodologies which will satisfy the reporting requirements defined for a breach in the event the data is lost, stolen, misplaced or an attempt made to hack the data.

a. The approved encryption method for data at rest (i.e., audio or video recorded sessions stored temporarily on a recording device, data stored on a workstation, laptop, USB thumb drive, remote Web-Server, data that resides in databases, file systems, and other structured storage methods) are based on the National Institute of Standards and Technology (NIST) Special Publication 800-111.

b. The approved encryption processes for data in motion (i.e., data that is moving through a network, including wireless transmission) are those that comply with Federal Information Processing Standards (FIPS) 140-2 and are included in NIST Special Publication 800-52, "Guidelines for the Selection and Use of Transport Layer Security (TLS) Implementations" and NIST Special Publication 800-77, "Guide to IPsec VPNs". For the transportation of sensitive information where the solution is maintained by a third-party vendor, the researcher must obtain a Business Associate (BA) contract with the vendor using language consistent with the HIPAA Final "Omnibus" Rule. The BA vendor is responsible for protecting the sensitive data from unauthorized access, including its own staff, and must comply with the Security and Breach Notification Rules.
c. The approved data destruction method is dependent on the type of media. Paper, film, and other hard copy media should be shredded or destroyed so that the PHI cannot be read or reconstructed. Electronic media should be cleared, purged or destroyed so that the PHI cannot be retrieved and be consistent with NIST Special Publication 800-88, "Guidelines for the Media Sanitation".

How does LACDMH evaluate the security of sensitive data or PHI?

1. LACDMH requires that computing devices used for the research and transportation of sensitive data meet federal (HIPAA) guidelines. The LACDMH CIOB verification process is accomplished through a risk assessment as described below:
   a. Evaluation of the computing devices used for accessing, processing or transporting sensitive data. Portable computer devices, laptops, notebooks, and tablets must be encrypted with a solution validated by NIST as meeting FIPS publication 140-2 and equipped with a strong and complex password.
   b. Ensure that all workstations, portable computing devices, and other systems that process and/or store sensitive data have a commercial third party anti-virus software solution and are updated when new anti-virus definition/software release is available. Additionally, ensure that the above-mentioned devices have current security patches applied and up-to-date.
   c. Encrypt all electronic sensitive files when the file is stored on any electronic portable devices or devices with removable media (e.g., USB thumb drives, floppies, CD/DVDs, SD Cards, digital audio or video recorders, etc.) using a vendor product validated by NIST as FIPS 140-2 compliant or simply use devices with encrypted hardware that are compliant with FIPS 140-2 (e.g., encrypted USB thumb drives, notebooks with encrypted hard-drives, encrypted audio recorders secured by a PIN, audio or video recording using webcam and microphone, and encrypted notebook with complex password security).
   d. Ensure that all emails containing sensitive information is sent via an encrypted method using a vendor product validated by NIST as FIPS 140-02 compliant.
   e. Smart Phone devices used by the research staff for the project must include encryption compliant to FIPS 140-2. The device must be locked if not in use and accessed by a complex password. The web browser's caching must be disabled. The device must have remote wipe capability in an event it is misplaced or lost. Texting information that may include any of the above HIPAA identifiers is strictly prohibited. The non-sensitive texts should have a statement warning clients to never respond, forward or reply to the text and delete it once read.
   f. Evaluation of the transportation method(s) for existence of adequate safeguards to secure the sensitive information from unauthorized access during transportation/transmittal. For solutions

utilizing the internet/webservers, security measures such as Valid SSL Certificates, Security Protocols, Authentication Methods, Cipher strength, and FIPS Compliance will be tested and evaluated.

g. Evaluation of the data workflow determines if the path that the sensitive information travels from creation until delivery to authorized recipients includes sufficient protection to render the data unusable, unreadable or indecipherable to unauthorized access.

2. LACDMH requires that the research project investigator use role-based access controls for all user authentications, enforcing the principle of least privilege to protect the sensitive information from unauthorized persons. Only the minimum necessary amount of PHI required to perform necessary functions, as defined by HIPAA Rule, may be copied, downloaded, or exported by the research staff.

3. The research project investigator is expected to maintain an automated audit trail which can identify the user or a system process which initiates any level of access to PHI. The audit trail must be date and time stamped, log both successful and failed accesses, is read only, and restricted to authorized users. If PHI is stored in a database, database logging functionality must be enabled.

Do I need to complete Section 4 – Privacy Assessment Form and Section 5 – Electronic Data Request/CIOB Assessment Form?

Yes, both forms must be completed by all investigators. Unsigned forms should be submitted with your HSRC Application. HSRC will forward the forms to the appropriate individuals.

PART II - APPLICATION DOCUMENTS

SECTION 1 - INVESTIGATOR ASSURANCE

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 for investigators including, but not limited to, the following:

PART A: 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 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.
9. 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.
10. 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).
11. Submit abstracts and/or manuscripts to the DMH HSRC for review prior to submission for publication.
12. Provide copies of all publications resulting from the research project.
13. Maintain current IRB renewals.
14. 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.”
15. Inform all co-investigators, research staff, employees, and LACDMH staff assisting in the conduct of the research of their obligations in meeting this Assurance.

PART B: DATA SECURITY ATTESTATION

1. Understand that project approval applies only to the protocol processes documented in the HSRC Application including the Privacy and Security Assessment 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 DMH HSRC Application "Assurance" section.

I verify that the information provided in this HSRC Application for Research is accurate and complete.

Project Title: _____

PRINTED Name of Principal Investigator: Click here to enter text.

SIGNATURE of Principal Investigator: Click here to enter text.

Date: Click here to enter text.

SECTION 2 - APPLICATION FOR RESEARCH

PRINCIPAL INVESTIGATOR INFORMATION

- Principal Investigator's Name: Click here to enter text.
- E-mail: Click here to enter text.
- Phone: Click here to enter text.
- Mailing Address: Click here to enter text.
- City: Click here to enter text. State: Click here to enter text. Zip Code: Click here to enter text.
- Name of Institution: Click here to enter text.
- Department: Click here to enter text.

DMH CO-INVESTIGATOR(S) AND/OR STAFF

Note: 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 a minimum, include individuals who recruit or consent participants or who collect study data. Omit co-investigators who are not employed by DMH.

- 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.
- Mailing Address: Click here to enter text.
- City: Click here to enter text. State: Click here to enter text. Zip Code: Click here to enter text.
- Research Role/Activities Performed:
- Click here to enter text.

Instructions: Check applicable boxes and provide a brief description to all questions. Please note that responses beyond the word limit will require revision and result in delay of review.

1. Project Title: Click here to enter text.
2. Are you a part-time or full-time faculty member of a college or university? Yes ☐ No ☐
   - If yes, which college or university: Click here to enter text.
3. Is your research project IRB approved? Yes ☐ No ☐ Exempt ☐
4. Research project funding status:
   Already Funded ☐ In the Process of Securing Funding ☐ Not Funded/Self-Funded ☐
5. The research activities will include staff/participants/data collection at:
   ☐ DMH Directly-Operated Program(s)
   ☐ LE Contractor(s)
   ☐ Both DMH Directly-Operated Program(s) and LE Contractor(s)
   ☐ Electronic Data Only

6. Description of research: (20 words or less for each item below)
   Geographic Area (include service area):
   - Click here to enter text.

   Demographics of participants (age, ethnicity, gender, language):
   - Click here to enter text.

   Service(s) to be studied/Intervention:
   - Click here to enter text.

   Sample Size: Click here to enter text.

   Special/Vulnerable Populations (disabilities, detention, underrepresentation):
   - Click here to enter text.

7. Research project study type (check all that apply):
   Experimental ☐ Observational/Survey ☐ Placebo ☐ Control Group ☐
   Other (20 words or less): Click here to enter text.

8. Resources requested from LACDMH:
   Staff Time ☐ Clinic/Office Space ☐ Electronic Data Extraction ☐ None ☐
   Other (20 words or less): Click here to enter text.

9. Indicate if your research project uses any of the following:

Electronic Data	Yes ☐	No ☐
Audio Recordings	Yes ☐	No ☐
Video Recordings	Yes ☐	No ☐
LACDMH Directly-Operated Clinic Space	Yes ☐	No ☐

10. Summarize your relevant research experience. (100 words or less)
    - Click here to enter text.
11. What is the research question? (100 words or less)
    - Click here to enter text.
12. Provide an abstract of your research project, including any specific benefits to LACDMH clients. (300 words or less)
    - Click here to enter text.
13. What are the specific benefits to:
    - DMH: Click here to enter text.
    - LA County: Click here to enter text.

RESEARCH SITE (Use page 27 of this application to enter information on additional sites.)

- LACDMH Service Area: Click here to enter text.
- Letter of Support submitted for each site Yes ☐ No ☐
- Name of Manager: 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.
- Service Area Address: Click here to enter text.
- City: Click here to enter text. State: Click here to enter text. Zip Code: Click here to enter text.

DOES THE INVESTIGATOR HAVE A ROLE BELOW AT THE REASEARCH SITE:

- LACDMH Employee Yes ☐ No ☐
- LACDMH Consultant Yes ☐ No ☐
- Other (brief explanation): Click here to enter text.

DESCRIPTION OF THE ROLE OF THE SITE(S) IN THE RESEARCH PROJECT:

- Recruitment Yes ☐ No ☐
- Obtaining Informed Consent Yes ☐ No ☐
- Treatment/Intervention Yes ☐ No ☐
- Other (brief explanation): Click here to enter text.

FUNDING OR OTHER SUPPORT (List Funding Source and/or Non-Monetary Support)

FUNDING SOURCE	AMOUNT
Click here to enter text.	$ Click here to enter text.
Click here to enter text.	$ Click here to enter text.

NON-MONETARY TYPE OF SUPPORT	SOURCE
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.

CONFLICT OF INTEREST

- Does any investigator, staff, or their immediate family members have a financial interest (including salary or other payments for services, equity, or intellectual property rights), that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research?

  Yes ☐ No ☐

  If yes, briefly explain:

  - Click here to enter text.
  - County Policy 608.02, states that "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."

    I acknowledge Yes ☐ No ☐

SECTION 3– LETTER(S) OF SUPPORT FORM

Instructions: Complete questions 1 through 8, and obtain one form for each research site. Letter(s) of Support are required for both LACDMH directly-operated sites, as well as LE contracted sites. Attach all applicable letter(s) with signatures in this section.

1. Principal Investigator: Click here to enter text.
2. Research Study Title: Click here to enter text.
3. Program/Clinic Site (including Service Area): Click here to enter text.
4. Description of the role of the site in the research project:
   - Recruitment ☐
   - Obtaining Informed Consent ☐
   - Treatment/Intervention ☐
   - Other (brief explanation): Click here to enter text.
5. Expected Research Start and Finish Date: Click here to enter text. to Click here to enter text.
6. Resources Requested, including Directly-Operated and LE Contract Providers (20 words or less): Click here to enter text.
7. Expected Impact at this Program (50 words or less): Click here to enter text.
8. All research staff on site at LACDMH directly-operated clinics are required to register as volunteers with LACDMH Human Resources prior to beginning any research activity. The program manager is responsible for ensuring appropriate supervision, per DMH Policy 600.11.
   Yes ☐ No ☐ N/A ☐

NO RESEARCH ACTIVITY CAN BEGIN BEFORE FINAL APPROVAL FROM THE HSRC

Your signature below indicates you have reviewed the research proposal above and intend to support the project with the necessary resources. In cases where LE contracted sites are involved, program head signator must have authority equivalent to a program head/clinic manager or above, and signatures from the district chief and deputy director responsible for overseeing their contracts are required. Note: County Policy 608.02, states that "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 Head: Print name legibly here.
Signature: _____ Date: _____
District Chief: Print name legibly here.
Signature: _____ Date: _____
Deputy Director: Print name legibly here.
Signature: _____ Date: _____

SECTION 4 – PRIVACY ASSESSMENT FORM

Instructions: Please refer to the Data Privacy and Security Guidelines, and make note of the bullet points below. All Investigators are required to complete this section.

- Data is considered de-identified if the Los Angeles County Department of Mental Health (LACDMH) Chief Information Office Bureau (CIOB) is providing and de-identifying data or none of the 18 HIPAA identifiers are collected.
- If LACDMH CIOB is not providing or de-identifying the data, appropriate security measures must be taken by the investigator. All data not de-identified by CIOB which may contain identifiers (coded or not) are treated as Protected Health Information (PHI).
- Research is required to be in compliance with federal HIPAA laws and LACDMH policy.

1. Principal Investigator: Click here to enter text.
2. Research Study Title: 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 name, e-mail address, and telephone number)
   - ☐ DMH Directly-Operated Clinics • Click here to enter text.
   - ☐ DMH Headquarters DMH Executives and CIOB • Click here to enter text.
   - ☐ DMH LE Contract Providers • Click here to enter text.
   - ☐ Directly from Clients • Click here to enter text.
4. Has the research project been issued a Certificate of Confidentiality? If yes, please attach it.
   Yes ☐ No ☐
5. Does the project include audio recordings? Yes ☐ No ☐
   - If yes, describe your plan to maintain privacy and security.
     - Click here to enter text.
6. Does the project include video recordings? Yes ☐ No ☐
   - If yes, describe your plan to maintain privacy and security.
     - Click here to enter text.
7. Does the research contain any of the 18 HIPAA identifiers? Yes ☐ No ☐
8. How long will the PHI be stored? Click here to enter text.
9. What methods of destructions will be used when discarding both electronic and paper documents with PHI?
   - Click here to enter text.

NO RESEARCH ACTIVITY CAN BEGIN BEFORE FINAL APPROVAL FROM THE HSRC

The DMH Privacy Officer has reviewed the above 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.

DMH Privacy Officer (*Please Print*): Print name legibly here.

Signature: _____ **Date:** _____

SECTION 5 – ELECTRONIC DATA REQUEST/CIOB ASSESSMENT FORM

Instructions: Before completing this section, please carefully read the Data Privacy and Data Security Guidelines. All investigators are required to complete this section.

Part A – Data Security

1. Principal Investigator: Click here to enter text.
2. Research Study Title: Click here to enter text.
3. Contact information of the individual completing the form:

   Name: Click here to enter text.

   E-mail: Click here to enter text. Telephone: Click here to enter text.
4. How will the data be provided/collected? (Provide the contact information for each checked box below, including contact person name, e-mail address, and telephone number.)

   ☐ DMH Directly-Operated Clinics
   - Click here to enter text.

   ☐ DMH Headquarters/DMH Executives and CIOB
   - Click here to enter text.

   ☐ DMH LE Contract Providers
   - Click here to enter text.

   ☐ Directly from Clients
   - Click here to enter text.
5. Are you storing or transmitting data electronically? Yes ☐ No ☐
   If yes, thoroughly describe data storage and transport process workflow.
   - Click here to enter text.
6. How long will the PHI be stored?
   - Click here to enter text.
7. What methods of destructions will be used when discarding both electronic and paper documents with PHI?
   - Click here to enter text.
8. List summary of data elements/data fields requested. (20 words or less)
   - Click here to enter text.
9. If you are using an audio or video recording device, list the make/model of each device.
   - Click here to enter text.
10. If you are uploading PHI (including de-identified data) to a website, list the URL.
    - Click here to enter text.
11. Please indicate where you will be recruiting research participants. Include the facility name, address, and contact person for each clinic below:
    - LACDMH Directly Operated Facilities
      - Click here to enter text.
    - LACDMH LE Contract Providers
      - Click here to enter text.
    - Other
      - Click here to enter text.

12. Please indicate where you will be interviewing research participants. Include the facility name, address, and contact person for each clinic below:
    - LACDMH Directly Operated Facilities
        - Click here to enter text.
    - LACDMH LE Contract Providers
        - Click here to enter text.
    - Other
        - Click here to enter text.

NO RESEARCH ACTIVITY CAN BEGIN BEFORE FINAL APPROVAL FROM THE HSRC
LACDMH CIOB 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.

LACDMH CIOB Security Officer or Designee: Print name legibly here.

Signature: **Date:**

Part B – LACDMH CIOB Resources

1. Are you requesting any electronic data from LACDMH-CIOB? Yes ☐ No ☐
    - Resources requested from LACDMH-CIOB (20 words or less)
        - Click here to enter text.

LACDMH CIOB 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).

LACDMH CIOB Deputy Director Print name legibly here. **(if applicable, only):**

Signature:

Date:

Part C – LACDMH Clinical Informatics

1. Are you requesting any electronic data from LACDMH Clinical Informatics? Yes ☐ No ☐

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).

LACDMH Chief, Clinical Informatics Print name legibly here. **(if applicable, only):**

Signature: **Date:**

PART III – SUPPLEMENTAL APPLICATION DOCUMENTS

SECTION 6 – INCLUSION OF CHILDREN AS RESEARCH PARTICIPANTS

(complete and submit only if applicable)

Instructions: Check applicable boxes and provide a brief description (20 words or less) to all applicable questions.

Part A - 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.

Select **one** of the following (3) questions that best describes the research and provide the corresponding information:

1. Is the research **not greater** than minimal risk? Yes ☐ No ☐
   - Click here to enter text.
2. Is the research **more than** minimal risk and offers direct benefit for the child? If yes, answer below : Yes ☐ No ☐
   a. List of risk(s): • Click here to enter text.
   b. List of benefit(s): • Click here to enter text.
   c. Available alternate treatment • Click here to enter text.
3. Is the research more than minimal risk, and **does not** offer direct benefit for the child? Yes ☐ No ☐
   a. How does it **compare** to minimal risk?
   - Click here to enter text.
   b. Is the research experience reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations? Yes ☐ No ☐
   c. Will research produce generalizable knowledge about the child's disorder or condition that is of **vital significance** for the knowledge or treatment of the child's disorder or condition? Yes ☐ No ☐

Part B - Consent

4. What is the informed consent/assent process with children and their parents?
   - Click here to enter text.
5. Will the parents or guardians be present with the child during discussions of the research? Yes ☐ No ☐
6. Will participation continue beyond the child's 18th birthday? Yes ☐ No ☐
   If yes, what is the process to re-consent?
   - Click here to enter text.

7. Will sensitive or private information, except as required by law, be shared with parents/guardians? Yes ☐ No ☐

   If yes, please explain:

   - Click here to enter text.

8. Will any of the research participants be wards of the State or other agency or institution? Yes ☐ No ☐

Part C - Incentives

9. Will incentives be offered to the child? If yes, please list: Yes ☐ No ☐

   - Click here to enter text.

10 Will incentives be offered to the parent? If yes, please list: Yes ☐ No ☐

   - Click here to enter text.

SECTION 7 – INCLUSION OF NON-ENGLISH PARTICIPANTS IN RESEARCH

(complete and submit only if applicable)

Instructions: Make note of the bullet points below, and respond to questions 1 through 6 as applicable, providing a brief description (20 words or less).

- The consent forms (unless waived) must be written in a language understandable to the participant.
- Translation into a language other than English must be performed by a qualified translator.
- The HSRC will review the English version of the consent form, as well as all other documents seen by participants (e.g., recruitment materials, information sheets, surveys, etc.).

1. List the language(s) the participants will speak.
   - Click here to enter text.
2. List any investigator(s) and/or staff who are fluent in the language(s) of the participants.
   - Click here to enter text.
3. Describe how translation services during the participant recruitment processes will occur.
   - Click here to enter text.
4. Describe how translation services during the *consent* processes will occur.
   - Click here to enter text.
5. Describe how translation services will be provided throughout the study.
   - Click here to enter text.
6. Describe how research staff will respond to emergency questions or problems from non-English speaking participants.
   - Click here to enter text.

SECTION 8 – WAIVER OR ALTERATION OF CONSENT PROCESS

(complete and submit only if applicable)

Instructions: Make note of the bullet points below, then respond to questions 1 through 6 as applicable, providing a brief description (20 words or less). If the research involves a product regulated by FDA or the results of the research may be submitted to FDA as part of a marketing application, consent cannot be waived.

1. Is the research subject to FDA regulations (i.e., involves use of a food, drug, biological device)? Yes ☐ No ☐
2. Is the research subject to the approval of state or local government officials, and designed to study:
   a. public benefit Yes ☐ No ☐
   b. service programs Yes ☐ No ☐
   c. procedures for obtaining benefits under those programs Yes ☐ No ☐
   d. changes in or alternatives to those programs or procedures Yes ☐ No ☐
   e. changes in methods or levels of payment for benefits or services under those programs? Yes ☐ No ☐
   f. if yes, to the above (a, b, c, d, or e), explain why the research could not practicably be carried out without the waiver or alteration. Yes ☐ No ☐
      - Click here to enter text.

If the answer to both Nos. 1 and 2 above is "No", please complete question(s) 3, 4, 5, and 6, to request a Waiver or Alteration.

3. Explain how the research involves no more than minimal risk.
   - Click here to enter text.
4. Explain why the waiver or alteration will not adversely affect the rights or welfare of the participants.
   - Click here to enter text.
5. Explain why the research could not practicably be carried out without the Waiver or Alteration.
   - Click here to enter text.
6. Will the participants be provided with additional relevant information after participation? Explain why or why not. Yes ☐ No ☐
   - Click here to enter text.

SECTION 9 – WAIVER OF CONSENT DOCUMENTATION

(complete and submit only if applicable)

Instructions: Make note of the bullet points below, then respond to all questions 1 through 4. The participant should be asked whether he/she wants documentation linking the participant with the research. The participant's choice takes precedence. Answers to questions 2a and 2b, must be "No", or answers to questions 3a and 3b must be "Yes".

1.	Is the research subject to FDA regulations (i.e., involves use of a food, drug, biological device)?	Yes ☐	No ☐
2a.	Does the research present greater than minimal risk?	Yes ☐	No ☐
2b.	Does the research involve procedures for which written consent is normally required outside the research context?	Yes ☐	No ☐
3a.	Would the only record linking the participant and the research be the consent document?	Yes ☐	No ☐
3b.	Would the principal risk to the participant be potential harm resulting from a breach in confidentiality?	Yes ☐	No ☐

4. Explain why a Waiver of Consent Documentation is necessary to conduct the research (100 words or less):

- Click here to enter text.

SECTION 10 – WAIVER OF HIPAA RESEARCH AUTHORIZATION

(complete and submit only if applicable)

Instructions: Make note of the bullet points below, then check all applicable boxes and provide corresponding information. 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.
   a. Partial Waiver (recruitment purposes) Yes ☐ No ☐
   b. Full Waiver (entire research study) Yes ☐ No ☐
   c. Alteration (written documents) Yes ☐ No ☐
2. Provide details regarding PHI involved in the research (e.g., medical record number, diagnosis, test result, etc.):
   a. Describe the PHI accessed for the research, including the source.
      - Click here to enter text.
   b. Describe information that will be recorded and provide a copy of any data collection form(s).
      - Click here to enter text.
3. Explain how access to and/or use of the PHI is necessary to conduct the research.
   - Click here to enter text.
4. Explain how the PHI is the minimum necessary to achieve goals of the research.
   - Click here to enter text.
5. 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.
6. 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.
7. Will identifiers (or links to identifiable data) be destroyed? Yes ☐ No ☐ N/A ☐
   a. If yes, describe the plan to destroy the identifiers at the earliest opportunity. Include when and how identifiers will be destroyed.
      - Click here to enter text.
   b. 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.
      - Click here to enter text.
   c. If N/A, investigators will not record identifiers or create links or codes to connect the data.
8. Describe why a waiver or alteration (instead of written authorization) is needed to conduct the research.
   - Click here to enter text.

SECTION 11 – CONSENT CHECKLIST

(complete and submit only if applicable)

Instructions: All consent forms must include the following elements. Check all boxes to indicate inclusion.

1. Statement that the study involves research, explanation of the purposes of the research, expected duration of participation, description of the procedures to be followed, and identification of any procedures that are experimental. ☐
2. Description of any reasonably foreseeable risks or discomforts to the participant. ☐
3. Description of any benefits to the participant or to others that may reasonably be expected from the research. ☐
4. Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. ☐
5. Statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. ☐
6. Explanation of who to contact for answers to pertinent questions about the research and research participant's rights and who to contact in the event of a research-related injury to the participant. ☐
7. All consents should include a statement that: ☐
   "Clients served by the Los Angeles County Department of Mental Health directly-operated clinics or LE contractors with questions or concerns regarding the impact of their research activities on access to or quality of their usual care may contact the Los Angeles County Department of Mental Health Human Subjects Research Committee at (213) 639-6348."
8. Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled to, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. The research and consent processes should not interfere with DMH services, or treatment of clients. ☐
9. For research involving greater than minimal risk, an explanation about whether: (1) medical treatments are available if injury occurs and, if so, what they consist of or where further information can be obtained. (2) Compensation is available if injury occurs and, if so, an explanation as to what it consists of or where further information can be obtained. ☐
10. Any additional costs to the participant that may result from participation in the research. ☐
11. Consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant. ☐
12. Statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided. ☐

SECTION 12 – ADDITIONAL RESEARCH SITE(S)

(complete __only__ if applicable)

__Instructions__: Enter the requested information below.

RESEARCH SITE

- Program/Clinic Site (including Service Area): Click here to enter text.
- Letter of Support submitted for each site Yes: ☐ No: ☐
- Name of Manager: 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.
- Service Area Address: Click here to enter text.
- City: Click here to enter text. State: Click here to enter text. Zip Code: Click here to enter text.

RESEARCH SITE

- Program/Clinic Site (including Service Area): Click here to enter text.
- Letter of Support submitted for each site Yes: ☐ No: ☐
- Name of Manager: 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.
- Service Area Address: Click here to enter text.
- City: Click here to enter text. State: Click here to enter text. Zip Code: Click here to enter text.

RESEARCH SITE

- Program/Clinic Site (including Service Area): Click here to enter text.
- Letter of Support submitted for each site Yes: ☐ No: ☐
- Name of Manager: 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.
- Service Area Address: Click here to enter text.
- City: Click here to enter text. State: Click here to enter text. Zip Code: Click here to enter text.

PART IV – ATTACHMENTS

ATTACHMENTS

Instructions: Complete and submit Attachments as applicable, then scan into one PDF document with corresponding attachments.

1. **CONSENT DOCUMENTS**
   Attach all applicable Consent Documents.

2. **RECRUITMENT MATERIALS**
   Attach any Recruitment Materials.

3. **DATA COLLECTION SUMMARY**
   Attach only the following (do not submit copies of each measure/instrument unless requested):
   a) List of standardized measures
   b) List of survey/interview questions that might be sensitive in nature
   c) A summary (50 words or less) of survey/interview questions

4. **HIPAA RESEARCH AUTHORIZATION FORM(S)**
   Instructions: Attach HIPAA Research Authorization Form(s) for LACDMH Directly-Operated programs only, as applicable here. Please see link below for the form:

   http://lacdmh.lacounty.gov/Policies/docs/500_01_att1.pdf

5. **BIO-SKETCH**
   Attach Bio-Sketch/Curriculum Vitae of Principal Investigator. If using curriculum vitae, please limit to five-double sided pages.

6. **INSTITUTIONAL REVIEW BOARD (IRB) DOCUMENTS**
   Attach both submitted IRB Application and IRB Approval Letter.