



## LOS ANGELES COUNTY DEPARTMENT OF MENTAL HEALTH



### HUMAN SUBJECTS RESEARCH COMMITTEE (HSRC) APPLICATION

**Project Title:** [Click here to enter text.](#)

**Principal Investigator:** [Click here to enter text.](#)

**Date of Submission:** [Click here to enter text.](#)

**Protocol No:**



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## OVERVIEW

*(Please read carefully)*

### 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. This includes LACDMH directly-operated programs and programs with LACDMH legal entity agreements. Research that exclusively studies LACDMH legal entity contractors' staff is exempt from HSRC review. Research activities cannot begin until HSRC approval is obtained.

Directly-Operated Clinic: Directly-operated clinic program sites are operated and managed with LACDMH employed staff.

Legal Entity Contract Provider: Legal entity contract providers are funded by LACDMH, but operated and managed by private organizations. Legal entity contract providers provide direct services to clients.

2. If the research does not involve Human Subjects as defined by federal guidelines and LACDMH Mental Health Review Policy No. 109.01, Section 2.2, then it does not require 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 generalized 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 or presentation), require HSRC review. Results do not have to be published or presented to qualify the activity as research.
4. 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, do not require HSRC review.



### What general criteria is necessary to apply for HSRC review?

1. The LACDMH HSRC exclusively 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' home institutes have registered IRBs, and that investigators complete the IRB approval process through these registered IRBs.

### How do I apply for HSRC approval?

1. Priority Review Process: This HSRC process prioritizes applications based on the relevance of the research question to LACDMH's mission, any potential research risks, and the resources requested. Investigators must fill out the Research Priority Review Form and their applications must be deemed priority by the LACDMH Executive Management Team before these applications are reviewed by the HSRC for approval. Once an application is prioritized, the HSRC will schedule a meeting, at which time the principal investigator must be available either in-person, or 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. 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 institute's registered IRB, required documents, supporting letters, and applicable forms.
3. 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 legal entity contracted sites. Attach all applicable letter(s) with signatures in this section. For legal entity 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 request additional information before granting research approval.
4. Volunteer Registration: Upon HSRC approval of the application for research approval, all 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 identify a DMH employee as a volunteer supervisor for the research project site. Volunteers must register with LACDMH Human Resources.
5. Exempt Application: If your research proposal meets one or more of the six federally outlined exempt category(s), please complete Section 18 –Exempt Categories. Though your project may have received an exempt approval/review from your home institution, the HSRC may require you to complete a full application under certain circumstances where additional information is needed to make determination.



**What do investigators need to know regarding data privacy?**

Data is de-identified only if it does not contain any of the following 18 HIPAA identifiers

1. Names	10. Account numbers
2. Geographic subdivisions smaller than a State (address, city council, etc.)	11. Certificate/license numbers
3. Dates related to birth, admission, discharge, death, and all ages over 89	12. Vehicle identifiers
4. Telephone numbers	13. Device identifiers and serial numbers
5. Fax numbers	14. Web universal resource locators (URLS)
6. E-mail addresses	15. Internet protocol (IP) address numbers
7. Social Security numbers	16. Biometric identifiers including finger/voice prints
8. Medical record numbers	17. Full face photographic images
9. Health plan beneficiary numbers	18. Any other unique identifying number, characteristic, or code, except for a code of other means of re-identification (for purposes of de-identifying).

**What does LACDMH require of investigators to safeguard PHI?**

1. LACDMH requires compliance with “The Health Information Technology for Economic and Clinical Health Act”. (HITECH) HITECH Act of 2009 defines Protected Health Information (PHI) as “rendered, unusable, unreadable, or indecipherable” if the data is either encrypted or destroyed by approved technology or methodologies which will provide a safe haven from 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., 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”
  - 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 be 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”



## Human Subjects Research Committee (HSRC)

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2. LACDMH requirements for the transportation method of the sensitive data are simply to be in compliance with the above Federal Guidelines. The LACDMH CIOB verification process is accomplished through a risk assessment as described below:
  - a. Security Assessment of the transportation method in verifying the existence of adequate safeguards which are enforced by up to date technology that secures sensitive information by unauthorized access during transportation and storage.
  - b. 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.

### What security measures does LACDMH use to evaluate website/server security?

1. Security measures include: (1) Valid Certificates, (2) Security Protocols, (3) Authentication, (4) Cipher Suites, (5) Patches, (6) Vulnerabilities, (7) PCI Compliance, and (8) FIPS Compliance.

### Other Important Information

1. Posting of Recruitment Flyers: Only those research studies approved by the LACDMH HSRC may post recruitment flyers in LACDMH contracted or directly-operated facilities.
2. 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.
3. HSRC Contact Information:  
Phone: (213) 639-6348  
E-mail address: [hsrc@dmh.lacounty.gov](mailto:hsrc@dmh.lacounty.gov)



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### ASSURANCE

I, the Principal Investigator, agree to follow all applicable policies and procedures of the Los Angeles County Department of Mental Health and 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:

1. Initiate the research only after HSRC approval of the Application for Research has been received.
2. Ensure that all research staff members collecting data 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 a Continuing Research Application 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. 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.
9. 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).
10. Submit abstracts and/or manuscripts to DMH for review prior to submission for publication.
11. Provide copies of all publications resulting from the research project.
12. Provide a Final Study Report to the HSRC when all research activities have ended.
13. Maintain active outside IRB renewals.
14. Inform all co-investigators, research staff, employees, and LACDMH staff assisting in the conduct of the research of their obligations in meeting this Assurance.

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

**PRINTED Name of Principal Investigator (or Advisor):** [Click here to enter text.](#)

**Date:** \_\_\_\_\_

**SIGNATURE of Principal Investigator (or Advisor):** \_\_\_\_\_



## APPLICATION CHECKLIST

Please check one category (complete, incomplete, N/A) for every section.

Section No.	SECTION NAME	COMPLETE	INCOMPLETE	N/A
<b>PART A: APPLICATION DOCUMENTS</b>				
1	Research Priority Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Application for Research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>PART B: SUPPLEMENTAL APPLICATION DOCUMENTS</b>				
3	Inclusion of Children in Research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Non-English Speaking Participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Waiver or Alteration of Consent Process	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Waiver of Consent Documentation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Waiver of HIPAA Research Authorization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Consent Checklist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Additional Research Site(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>PART C: ATTACHMENTS</b>				
10	IRB Documents (IRB Application and IRB Approval Letter)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	LACDMH Letter(s) of Support Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Privacy Letter of Support Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	Electronic Data Request/DMH-CIOB Letter of Request Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	Bio-sketch	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	Consent Document Form(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	HIPAA Research Authorization Form(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17	Recruitment Material(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18	Data Collection Summary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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19	Exempt Categories	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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**PART A - APPLICATION DOCUMENTS**



## SECTION 1 – RESEARCH PRIORITY REVIEW

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

1. Principal Investigator's Name: [Click here to enter text.](#)
2. Project Title: [Click here to enter text.](#)
3. 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.](#)
4. Is your research project IRB approved? Yes  No  Exempt
5. Research project funding status:  
Already Funded  In the Process of Securing Funding  Not Funded/Self-Funded
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 method (check all that apply):  
Experimental  Observational  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   
Other (20 words or less): [Click here to enter text.](#)
9. Indicate if your research project uses any of the following:

**Note:** If you check yes for "Electronic data", or "Audio/Video recordings", please complete Section 12 – Electronic Data Request/DMH-CIOB Letter of Support.

- Protected Health Information (PHI) Yes  No
- Electronic Data Yes  No



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- Audio/Video Recordings                      Yes       No
- LACDMH Directly-Operated Clinic Space      Yes       No

10. Summarize your relevant research experience. (50 words or less)

- [Click here to enter text.](#)

11. What is the research question? (20 words or less)

- [Click here to enter text.](#)

12. Provide an abstract of your research project, including any specific benefits to LACDMH clients. (100 words or less)

- [Click here to enter text.](#)

### FOR HSRC USE ONLY

#### **HUMAN SUBJECTS RESEARCH COMMITTEE**

1. What are the specific benefits to:

DMH: [Click here to enter text.](#)

LA County: [Click here to enter text.](#)

2. Are there additional resources needed (i.e. staff time, facility use)?                      Yes       No

3. Recommendations: [Click here to enter text.](#)

#### **HUMAN SUBJECTS RESEARCH COMMITTEE CHAIR**

**PRINTED Name:** [Click here to enter text.](#)

**Date:** \_\_\_\_\_



## SECTION 2 - APPLICATION FOR RESEARCH

**Instructions:** Check applicable boxes and provide a brief description to all applicable questions.

### 1. PRINCIPAL INVESTIGATOR INFORMATION

- E-mail: [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.](#)
- Phone: [Click here to enter text.](#)

### 2. 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. Please omit co-investigators who are not employed by DMH.

- Co-Investigator: [Click here to enter text.](#)
- E-mail: [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.](#)
- Title/Position: [Click here to enter text.](#)
- Phone: [Click here to enter text.](#)

### 3. RESEARCH SITE (Please use page 22 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.](#)
- E-mail: [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.](#)
- Title/Position: [Click here to enter text.](#)
- Phone: [Click here to enter text.](#)



**4. DOES THE INVESTIGATOR HAVE A ROLE BELOW AT THE RESEARCH SITE:**

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

**5. 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.](#)

**6. 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.](#)

**7. 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.](#)



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**PART B - SUPPLEMENTAL APPLICATION DOCUMENTS**

**Instructions: Complete and submit Supplemental Application Documents,  
Section(s) 3 through 9, as applicable.**

### SECTION 3 – INCLUSION OF CHILDREN AS RESEARCH PARTICIPANTS

*(Complete 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 18<sup>th</sup> birthday? Yes  No   
 If yes, what is the process to re-consent?



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- [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 4 – INCLUSION OF NON-ENGLISH PARTICIPANTS IN RESEARCH

*(Complete 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.).
- Translated documents, as well as qualifications of the translator, must be submitted to the HSRC for approval.

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 5 – WAIVER OR ALTERATION OF CONSENT PROCESS

*(Complete 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 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.](#)

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*If the answer to both of questions above to Nos. 1 and 2 is “No”, please complete the below question(s) 3, 4, 5, and 6, to request 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.](#)



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## SECTION 6 – WAIVER OF CONSENT DOCUMENTATION

*(Complete only if applicable)*

**Instructions:** Make note of the bullet point below, then respond to questions 1 through 3 as applicable.

- The participant should be asked whether he/she wants documentation linking the participant with the research. The participant's choice is takes precedence.

1. Is the research subject to FDA regulations (i.e., involves use of a food, drug, biological device)? Yes  No 
  - If yes, answer question 2 below to request waiver of consent documentation.
  - Both answers to question 2a and 2b, must be “No” for a Waiver of Consent Documentation.
  - If no, answer question 2 *or* question 3 to request Waiver of Consent documentation.
  - Both answers to Nos. 3a and 3b must be “Yes” for a Waiver of Consent Documentation.
2. a. Does the research present greater than minimal risk? Yes  No
- b. Does the research involve procedures for which written consent is normally required outside the research context? Yes  No
3. a. Would the only record linking the participant and the research be the consent document? Yes  No
- b. Would the principal risk to the participant be potential harm resulting from a breach in confidentiality? Yes  No

## SECTION 7 – WAIVER OF HIPAA RESEARCH AUTHORIZATION

*(Complete only if applicable)*

**Instructions:** Make note of the bullet point 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 results, 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 8 – CONSENT CHECKLIST

*(Complete only if applicable)*

**Instructions:** In all research studies where investigators propose using consent forms, the consent process 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 the statement that:   
“Clients of the Los Angeles County Department of Mental Health with questions or concerns regarding 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, 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.



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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 9 – ADDITIONAL RESEARCH SITE(S)

*(Complete only if applicable)*

**Instructions:** Check applicable boxes and provide a brief description to all applicable questions.

#### RESEARCH SITE

- 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.](#)

#### RESEARCH SITE

- 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.](#)

#### RESEARCH SITE

- 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.](#)



**PART C - ATTACHMENTS**

**Instructions: Complete and submit Attachments as applicable, then scan Part C into one PDF document with each cover page in front of the corresponding attachment.**



## SECTION 10 – INSTITUTIONAL REVIEW BOARD (IRB) DOCUMENTS

Instructions: Attach both submitted IRB application and IRB Approval Letter here, if applicable.



## SECTION 11 – LETTER(S) OF SUPPORT FORM

**Instructions:** Complete questions 1 through 7, and obtain one form for each research site. Letter(s) of support are required for both LACDMH directly-operated sites, as well as legal entity 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 Legal Entity Contractor 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.](#)

### NO RESEARCH ACTIVITY CAN BEGIN BEFORE FINAL APPROVAL FROM THE HSRC

Please provide your signature below to indicate you have reviewed the research proposal above, and support the research project. In cases where legal entity contractor 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.

Program Head: [Click here to enter text.](#)

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

District Chief [Click here to enter text.](#)

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Deputy Director: [Click here to enter text.](#)

Signature: \_\_\_\_\_

Date: \_\_\_\_\_



**Human Subjects Research Committee (HSRC)**

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**SECTION 12 – PRIVACY LETTER OF SUPPORT FORM**

*(Complete only if applicable)*

**Instructions:** Please make note of the bullet points below.

- Send this completed form, and the HSRC application, to Veronica Jones at (213) 739-2375.
- Data is considered de-identified only if the Los Angeles Chief Department Mental Health (LACDMH) Chief Information Office Bureau (CIOB) is providing and de-identifying data.
- If LACDMH CIOB is not providing or de-identifying the data, appropriate security measures must be taken by the investigator. LACDMH treats all data not de-identified by CIOB as Protected Health Information (PHI).
- Investigators' 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?

LACDMH CIOB  Investigator collects directly from client and/or provider

4. Are you using audio recordings? Yes  No

- If yes, describe your plan to maintain privacy and security
  - [Click here to enter text.](#)

5. Are you using video recordings? Yes  No

- If yes, describe your plan to maintain privacy and security
  - [Click here to enter text.](#)

6. Does the research contain any of the 18 HIPAA identifiers? Yes  No

**NO RESEARCH ACTIVITY CAN BEGIN BEFORE FINAL APPROVAL FROM THE HSRC**

The Privacy Officer has reviewed the above plan for protecting client data, and has determined the plan meets the minimum requirements to proceed with the data request.

**Privacy Security Officer (Please Print):** [Click here to enter text.](#)

Signature: \_\_\_\_\_

Date: \_\_\_\_\_



**SECTION 13 – ELECTRONIC DATA REQUEST / DMH-CIOB LETTER OF SUPPORT FORM**  
*(Complete only if applicable)*

**Instructions:** In order to complete this section, please contact the LACDMH Chief Information Office Bureau (CIOB) Security Officer at (213) 251-6461 or (213) 251-6480.

1. Principal Investigator: [Click here to enter text.](#)
2. Research Study Title: [Click here to enter text.](#)
3. Are you:
  - Requesting data from CIOB Yes  No 
    - Resources requested from DMH-CIOB (20 words or less)
      - [Click here to enter text.](#)
  - Storing or transmitting data electronically Yes  No 
    - If yes, thoroughly describe data storage and transport process workflow
      - [Click here to enter text.](#)
4. List summary of data elements/data fields requested (20 words or less)
  - [Click here to enter text.](#)
5. If you are using an audio or video recording device, list the make/model of each device
  - [Click here to enter text.](#)
6. If you are uploading PHI (including de-identified data) to a website, list the URL
  - [Click here to enter text.](#)

**NO RESEARCH ACTIVITY CAN BEGIN BEFORE FINAL APPROVAL FROM THE HSRC**

LACDMH CIOB has reviewed feasibility of the proposed research study, and gives approval to proceed with data request.

LACDMH CIOB Security Officer (*Please Print*): [Click here to enter text.](#)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_



**SECTION 14 – BIO-SKETCH**

**Instructions: A NIH formatted bio-sketch is required for application submission. Attach bio-sketch here.**

## **SECTION 15 – CONSENT DOCUMENTS**

**Instructions: Check and attach here all applicable Consent Documents.**

- Consent**
  
- Assent**
  
- Permission Forms**
  
- Translated Documents**
  
- Verbal Script(s)**
  
- Information Sheet(s)**



**SECTION 16 – HIPAA RESEARCH AUTHORIZATION FORM(S)**

**Instructions: Attach HIPAA Research Authorization Form(s) for  
LACDMH Directly-Operated programs only, as applicable.**



**SECTION 17 – RECRUITMENT MATERIALS**

**Instructions: Attach any Recruitment Materials here.**

## **SECTION 18 – DATA COLLECTION SUMMARY**

**Instructions: Attach only the following (Do not submit copies of each measure/instrument):**

- 1. List of standardized measures**
- 2. List of survey/interview questions that might be sensitive in nature**
- 3. A summary (50 words or less) of survey/interview questions**

## SECTION 19 – EXEMPT CATEGORIES

**Instructions:** If your research proposal was approved exempt by your home IRB institution, please check one or more of the federal outlined exempt categories that best describes your research project.

### Exempt Category 1

Research is conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- a. Research on regular and special education instructional strategies
- b. Research on the effectiveness of or the comparison among instructional techniques, curricular or classroom management methods.

### Exempt Category 2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, only if:

- a. Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects: 
  - Subject records/responses will be anonymous. Identifiers (name, ID number, phone number, address, audio/video recordings, etc.) will not be received / collected.
  - Individually identifiable information will be obtained. However, the identifiers (name, code, ID #, address, etc.) will not be recorded. 
    - o Describe how the obtained information will be recorded, maintained, secured, and how/when identifiable information will be destroyed.
      - [Click here to enter text.](#)
- b. And any disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employment or reputation [for students – their academic standing].

#### Note:

- If the research involves children as participants, the research must be limited to education tests (cognitive, diagnostic, aptitude, achievement), and observation of public behavior when the investigator(s) do not participate in the activities being observed.
- Research that uses survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities where children are being observed cannot be granted an exemption.

**Exempt Category 3**

Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under above Exempt Category 2:

- a. The human subjects are elected or appointed public officials or candidates for public office
- b. Federal Statute(s) require(s) without exemption that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**Exemption Category 4**

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if:

- a. These sources are publicly available.
- b. The information is recorded by the investigator in such a manner that subjects cannot be identified, directly, or through identifiers linked to the subjects.
- c. Data documents, records, pathological specimens or diagnostic specimens to be received are:
  - Anonymous: Without identifiers, such as name, ID number, linking code, phone number, address, audio/video recordings, etc. A code is not applied by the provider (source).
  - Coded: With linking codes. A code that is linked to the subjects' identifiable information is generated and maintained by the provider (source). The provider also retains the key to the code and will not provide the key or divulge the identity of the subjects to the researchers.
  - Identifiable: With identifiers, such as name, ID number, phone number, address, audio/video recordings, etc.
- d. If the information to be received is coded or identifiable, describe how the obtained information will be recorded, maintained, secured, and how/when the linking code will be destroyed.
  - [Click here to enter text.](#)
- e. Identify the source(s) of the data, documents, records, pathological specimens, or diagnostic specimens.
  - [Click here to enter text.](#)
- f. Identify the timeframe for when the data, documents, records, pathological specimens, or diagnostic specimens you will receive were collected by the source(s).
  - [Click here to enter text.](#)

**Note:**

- Research involving review of medical records and/or protected health information (PHI) cannot be exempt from review.



**Exempt Category 5**

Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads and which are designed to study, evaluate, or otherwise examine:

- a. Public benefit or service programs
- b. Procedures for obtaining benefits or services under those programs
- c. Possible changes in or alternatives to those programs or procedures
- d. Possible changes in methods or levels of payment for benefits or services under those programs

**Exempt Category 6**

Taste and food quality evaluation and consumer acceptance studies.

- a. Wholesome foods without additives will be consumed
- b. A food will be consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the U.S. Food and Drug Administration or approved by the Environmental Protection Agency or the Food and Safety and Inspection Service of the U.S. Department of Agriculture
- c. Describe the food and, if applicable, the food ingredient
  - [Click here to enter text.](#)