**REQUEST FOR AMENDMENT FORM**

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| Protocol Title: | Click here to enter text. |
| Protocol Number: | Click here to enter text. |
| Request Date: | Click here to enter text. |
| Principal Investigator (PI): | Click here to enter text. |
| Primary Contact Person: | Click here to enter text. |
| Primary Contact Phone Number and Email: | Click here to enter text. |

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| 1. Amendment Description – Please select the type of amendment you are requesting (select all that apply):
 |
| [ ]  Change in protocol (design, methods, procedures, etc.) |
| [ ]  Change in currently approved consent/assent forms |
| [ ]  Change in data collection tools |
| [ ]  Change to number of participants and/or selection criteria |
| [ ]  Change in recruitment materials (flyers, brochures, emails, compensation, etc.) |
| [ ]  Change in study materials (surveys, questionnaires, etc.) |
| [ ]  Addition of study site(s): |
| [ ]  Change in research personnel |
| [ ]  Other Changes:Click here to enter text. |
| External Transcription Services: If the amendment includes a change regarding external transcription services, an Oath of Confidentiality agreement must be attached. If this doesn’t apply, please indicate N/A in the text box. Click here to enter text. |

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| 1. For each item selected above, please describe the proposed changes:
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| Click here to enter text. |

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| 1. For each item selected above, please state the rationale for the proposed changes:
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| Click here to enter text. |

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| 1. Potential risks to participants as a result of the amendment:
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| [ ]  Yes [ ]  No [ ]  Not Applicable |
| If yes, please explain the risks and how they will be handled:Click here to enter text. |

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| 1. Is there a change in benefits as a result of this amendment?
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| [ ]  Yes [ ]  No [ ]  Not Applicable |
| If yes, describe the expected benefits of this amendment:Click here to enter text. |

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| 1. Are the changes expected to affect participants’ willingness to participate in the research?
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| [ ]  Yes [ ]  No [ ]  Not Applicable |
| If yes, please explain. Click here to enter text. |

Please submit this form and all amended materials, including amended HSRC application **with changes highlighted and bolded** to [hsrc@dmh.lacounty.gov](file://///dmhhqfile1/home%24/NoPonce/FILE%20-%20Dr.%20Eisen/HSRC/hsrc%40dmh.lacounty.gov). If applicable, please attach the Approved Updated IRB Application and Approved Updated IRB Approval Notification.

I certify that the information provided entirely and accurately describes the proposed changes to the research protocol. I agree not to make any changes to the project during the approval period until external IRB approval and HSRC approval for these changes have been obtained.

PI Name: Click here to enter text.

PI Signature: Date: Click here to enter text.

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